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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON OPIOID STOCKHOLDER DERIVATIVE LITIGATION	Lead Case No. 3:19-cv-21330-FLW-LHG (Consolidated with Case No. 3:19-cv-21465-MAS-DEA)
This Document Relates To:	VERIFIED CONSOLIDATED STOCKHOLDER DERIVATIVE COMPLAINT FOR BREACH OF FIDUCIARY DUTY AND UNJUST ENRICHMENT

Plaintiffs Christopher Leagre and Tracy Bynum ("Plaintiffs"), located at 12851 Norfolk Circle, Carmel, Indiana, and 2100 Yucca Avenue, Fullerton, California, respectively, by their attorneys, submit this Verified Consolidated Stockholder Derivative Complaint for Breach of Fiduciary Duty and Unjust Enrichment. Plaintiffs allege the following on information and belief, except as to the allegations specifically pertaining to Plaintiffs, which are based on personal knowledge. This complaint is also based on the investigation of Plaintiffs' counsel, which included, among other things, a review of public filings with the U.S. Securities and Exchange Commission ("SEC") and a review of news reports, press releases, and other publicly available sources.

NATURE AND SUMMARY OF THE ACTION

1. This is a stockholder derivative action brought by Plaintiffs on behalf of nominal defendant Johnson & Johnson ("J&J" or the "Company") against certain of its officers and directors for breach of fiduciary duty, unjust enrichment, and violations of law. These wrongs resulted in billions of dollars in damages to J&J's reputation, goodwill, and standing in the business community. Moreover, these actions have exposed J&J to billions of dollars in potential liability for violations of law.

2. J&J and its subsidiaries manufacture, sell, and distribute a range of medical devices and pharmaceutical drugs, including opioids. Opioids are

categorized as "Schedule II Controlled Substances" due to their high potential for abuse and potential to cause severe psychological or physiological dependence. Given these risks, generally accepted standards of medical practice historically dictated that opioids be used only short-term—e.g., for acute pain, pain relating to recovery from surgery, or cancer or palliative care. In those instances, the risk of addiction is low or of little significance.

3. Beginning in the mid-1990s, J&J and other opioid developers (collectively, the "Opioid Manufacturers")[1] set out to enlarge the narrow opioid patient profile by reversing the traditional understanding of opioid use. To convince medical professionals to prescribe more opioids to a broader range of patients, the Opioid Manufacturers executed massive and unprecedented marketing campaigns that minimized the risks and exaggerated the benefits associated with the long-term use of opioids to treat wide-ranging conditions, including chronic noncancer pain. The Opioid Manufacturers: (i) deceptively promised that long-term opioid use would improve patients' function and quality of life; (ii) trivialized or obscured the serious risks and adverse outcomes, including the risk of addiction, overdose, and death, associated with opioid use; (iii) overstated the effectiveness of opioids compared with other treatments; and (iv) mischaracterized the difficulty of withdrawal from

[1] The "Opioid Manufacturers" refers to the following companies, collectively: J&J, Purdue, Actavis, Endo, Cephalon, Mallinckrodt, KVK-Tech, and Amneal.

opioids and the prevalence of withdrawal symptoms. The Opioid Manufacturers also deceptively marketed opioids for indications and benefits that were outside of the drugs' labels.

4. The Opioid Manufacturers' marketing and promotional efforts included, among other things, disseminating favorable "educational" materials; advertising in print materials and online; sponsoring continuing medical education courses; and hiring "key opinion leaders" to act as consultants and serve as lecturers. These efforts were intended to increase the market for opioids by influencing the prescribing behavior of physicians and convincing doctors to prescribe opioids for chronic noncancer pain.

5. The Opioid Manufacturers' deceptive marketing schemes were overwhelmingly successful, resulting in a dramatic shift in the medical and public consensus regarding the use of opioids. Between 1999 and 2010, sales of prescription opioids in the U.S. quadrupled. In 2012, health care providers wrote 259 million prescriptions for opioid painkillers—enough to medicate every adult in America around the clock for one month. Opioids—once a niche drug—are now the most prescribed class of drugs in the U.S.

6. The dramatic increase in opioid prescriptions to treat common chronic pain conditions has been catastrophic, causing a substantial rise in opioid overdose deaths and opioid addiction treatment admissions. Nationally, from 1999 through

2016, more than 350,000 people in the U.S. died from an overdose involving opioids. Over 200,000 of those deaths involved patients who were prescribed opioids to treat pain. In 2017, more than 70,000 people died of drug overdoses, and approximately two-thirds of those deaths were linked to opioids. According to the Centers for Disease Control and Prevention (the "CDC"), opioids have created a "public health epidemic."[2]

7. J&J played an integral role in fueling the opioid epidemic. Through its subsidiary, Janssen Pharmaceuticals, Inc. ("Janssen"), J&J aggressively and deceptively marketed the prescription opioids DURAGESIC®, NUCYNTA®, and NUCYNTA® ER for the long-term treatment of chronic pain. While these highly addictive narcotics have a potential for abuse similar to OxyContin and other Schedule II opioids, the Company marketed these products as "unlike traditional opioids" and as having "non-opioid" properties. J&J boasted that NUCYNTA and NUCYNTA ER were safer, milder, and less addictive than competitor products, like OxyContin.

8. The Company was well aware that these representations were false, deceptive, and unsupported by scientific evidence. In fact, the Company's own scientific advisors warned J&J that many of the marketing messages it used to

[2] CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 29, 2014), https://www.cdc.gov/washington/testimony/2014/t20140429.htm.

promote opioids generally, and its own products in particular, were misleading and should not be disseminated. The U.S. Food and Drug Administration ("FDA") also warned J&J that its marketing messages about opioids were misleading. In 2004, the FDA notified J&J that its marketing of DURAGESIC, a transdermal patch made out of the active pharmaceutical ingredient ("API") fentanyl, was deceptive and contained misleading and unsubstantiated claims about the effectiveness of the product and its potential for abuse. Yet, the Company continued to disseminate misleading messages about its products and opioids in general.

9. J&J further fueled the opioid epidemic by supplying other opioid manufacturers with APIs to be used in opioid drugs. From the 1990s through at least 2016, J&J, through its wholly owned subsidiaries Tasmanian Alkaloids Pty, Ltd. ("Tasmanian Alkaloids") and Noramco, Inc. ("Noramco"), supplied opioid APIs, including oxycodone, hydrocodone, morphine, codeine, and fentanyl, to other opioid manufacturers in the U.S. to be used in opioid drugs. By 2015, the Company's "Noramco World Wide Narcotics Franchise," comprised of Noramco and Tasmanian Alkaloids, was the number one supplier of narcotic APIs in the U.S. As a result, Janssen profited from the growth of both unbranded and branded opioids and was driven to develop the market as much as possible.

10. J&J's role in the opioid epidemic has subjected the Company to numerous lawsuits and governmental investigations. Since 2014, J&J and Janssen

have been named as defendants in more than 2,500 lawsuits brought by various state and local governments related to their marketing of opioids. Additionally, over 2,200 federal cases accusing J&J and others of unlawful marketing practices have been coordinated in a federal multidistrict litigation ("MDL") pending in the U.S. District Court for the Northern District of Ohio.[3] The Company has also received subpoenas or requests for information related to opioid marketing practices from a number of state attorneys general. In September 2017, the Texas and Colorado Attorney General's Offices contacted J&J on behalf of approximately thirty-eight states regarding a multistate Attorney General investigation. In August 2019, the U.S. Attorney's Office for the Eastern District of New York issued J&J a grand jury subpoena seeking documents related to the Company's anti-diversion[4] policies and procedures and distribution of opioid medications. And in September 2019, the Company received subpoenas from the New York State Department of Financial Services as part of its inquiry into the effect of opioid prescriptions of New York health insurance premiums.

[3] In re: National Prescription Opiate Litigation, MDL No. 2804 (N.D. Ohio).

[4] The term "diversion" refers to the Drug Enforcement Agency's requirements that drug registrants ensure drug security and recordkeeping, monitor the movement of licit controlled substances across U.S. borders, and issue import and export permits for that movement.

11. These lawsuits and investigations have exposed J&J to billions of dollars in liability and already cost the Company hundreds of millions of dollars in settlements and adverse judgments. Finding that J&J promulgated "false, misleading, and dangerous marketing campaigns" that "caused exponentially increasing rates of addiction, overdose deaths," and babies born exposed to opioids, in August 2019, an Oklahoma state judge ordered the Company to pay the state $465 million.[5] And on October 1, 2019, J&J announced that it had agreed to pay $20.4 million to resolve similar lawsuits brought by two Ohio counties. Then, in mid-October 2019, the Company reached an agreement in principle with four state attorneys general, pursuant to which the Company would pay ***$4 billion*** over two or three years to resolve lawsuits over its contribution to the opioid-crisis.

12. On April 18, 2019, pursuant to New Jersey law, Plaintiffs sent their respective letters to the J&J Board of Directors (the "Board") demanding that the Board investigate the foregoing facts and claims arising from them and commence litigation against the corporate fiduciaries responsible for damaging J&J (collectively, the "Demand").[6] In response, J&J's counsel, Sidley Austin LLP

[5] While Judge Thad Balkman originally ordered J&J to pay $572 million, he announced in November 2019 that there was an arithmetic error in the original order and reduced the judgment.

[6] Plaintiffs' Demand is attached hereto as Exhibit A.

("Sidley Austin"), sent Plaintiffs' counsel a letter stating that Lowenstein Sandler LLP ("Lowenstein") was investigating the "underlying matters regarding the Company's opioid products that are addressed in [the Demand]." Although the letter disclosed that Douglas Eakeley from Lowenstein was leading the investigation, it did not state who at J&J Mr. Eakeley was reporting to, nor whether the Board had established a committee to oversee the investigation. The letter provided little more detail concerning the investigation, beyond that it was "underway and is currently in the fact-gathering stage." Notably, the Company's letter did not delineate the scope of the investigation, nor the anticipated duration of the investigation. Neither did the Company's letter address whether the Board had secured tolling agreements from potential defendants, as plaintiffs have explicitly demanded. Plaintiffs' counsel's subsequent correspondence with counsel at Sidley Austin produced little more detail concerning the status of the investigation and the Board's involvement in the investigation. After nearly eight months without a substantive response or details of the supposed investigation from J&J's Board—far longer than the ninety days provided by statute—Plaintiffs' counsel commenced this derivative litigation.

13. Thereafter, on April 28, 2020, counsel at Sidley Austin sent a letter to Plaintiffs' counsel stating that Lowenstein had completed its investigation and

provided its findings to J&J's Board on April 13, 2020 (the "2020 Report").[7] Lowenstein recommended in its 2020 Report that J&J refuse Plaintiffs' Demand and that the Company not pursue any claims or otherwise seek any relief relating to Plaintiffs' allegations.

14. Ten days later, J&J's Board, with the exception of defendant Alex Gorsky ("Gorsky") (the "Demand Board"), met to consider the Demand and the 2020 Report detailing Lowenstein's investigation, findings, conclusions, and recommendations. Following the Demand Board's lone meeting, the Demand Board voted to adopt the 2020 Report's recommendations to refuse the demands and to not pursue litigation against or relief from any of the Company's fiduciaries.

15. The Demand Board's rejection of Plaintiffs' Demand was wrongful as a matter of law. The Demand Board's refusal was based on a *pro forma* review designed to ensure a predetermined result that would absolve defendants of any liability, without a good faith and reasonable examination of known material facts establishing the defendants' liability. Among other issues discussed at length in this Complaint, the decision by the Demand Board to hire Lowenstein to investigate the alleged wrongdoing demonstrates the Demand Board's lack of independence and lays bare its true intention: to avoid pursuing any claims demanded by Plaintiffs

[7] The 2020 Report is attached hereto as Exhibit H.

against the Company's purported fiduciaries. As the Demand Board was well aware, Lowenstein has a history of conducting perfunctory corporate investigations designed to exonerate J&J's officers and directors from all manner of wrongdoing. Consistent with its track record, Lowenstein again failed to conduct a good faith investigation of Plaintiffs' Demand here, instead opting in the 2020 Report to copy and paste entire sections verbatim from a prior report Lowenstein prepared for J&J in another matter and failing to consider material facts demonstrating defendants' liability. The Demand Board did not conduct any evaluation or take any steps to ensure that Lowenstein's prior investigation and findings exonerating J&J's fiduciaries in other matters would not affect the firm's ability to fairly and objectively consider Plaintiffs' Demand, allegations, and claims here. This was not by accident, but rather by design: the Demand Board, above all else, required an investigator who would recommend that no action be taken against the members of the Demand Board or any other purported fiduciaries of J&J—and the Company knew from prior experience that Lowenstein would be a willing and loyal dance partner. Unfortunately for J&J and its stockholders, the Demand Board was correct, and the serious and credible allegations and claims against the defendants were given short shrift, culminating in a cut-and-paste "report" that does not reflect a good faith and reasonable investigation of Plaintiffs' Demand.

16. For these reasons and the reasons discussed in greater detail below, the Demand Board's rejection of the Demand was wrongful and outside the ambit of the business judgment rule.

JURISDICTION AND VENUE

17. Jurisdiction is conferred by 28 U.S.C. §1332. Complete diversity among the parties exists and the amount in controversy exceeds $75,000, exclusive of interests and costs.

18. This Court has jurisdiction over each defendant named herein because each defendant is either a corporation that conducts business in and maintains operations in this District, or is an individual who has sufficient minimum contacts with this District to render the exercise of jurisdiction by the District courts permissible under traditional notions of fair play and substantial justice.

19. Venue is proper in this Court in accordance with 28 U.S.C. §1391 because: (i) J&J maintains its principal place of business in this District; (ii) one or more of the defendants either resides in or maintains executive offices in this District; (iii) a substantial portion of the transactions and wrongs complained of herein, including the defendants' primary participation in the wrongful acts detailed herein, and aiding and abetting and conspiracy in violation of fiduciary duties owed to J&J, occurred in this District; and (iv) defendants have received substantial

compensation in this District by doing business here and engaging in numerous activities that had an effect in this District.

THE PARTIES

Plaintiffs

20. Plaintiff Christopher Leagre was a stockholder of J&J at the time of the wrongdoing complained of, has continuously been a stockholder since that time, and is a current J&J stockholder. Plaintiff is a citizen of Indiana.

21. Plaintiff Tracy Bynum was a stockholder of J&J at the time of the wrongdoing complained of, has continuously been a stockholder since that time, and is a current J&J stockholder. Plaintiff is a citizen of California.

Nominal Defendant

22. Nominal defendant J&J is a New Jersey corporation with principal executive offices located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Accordingly, J&J is a citizen of New Jersey. J&J is a holding company with more than 260 operating subsidiaries. Through its subsidiaries, the Company engages in the research and development, manufacture and sale of products in the health care field. As of December 31, 2019, J&J had approximately 132,200 employees worldwide.

Defendants

23. Defendant Gorsky is J&J's Chairman of the Board and has been since December 2012; and Chief Executive Officer, Chairman of the Executive

Committee, and a director and has been since April 2012. Defendant Gorsky was also J&J's Vice Chairman of the Executive Committee from January 2011 to April 2012; a Member of the Executive Committee from January 2009 to January 2011; Worldwide Chairman, Medical Devices and Diagnostics Group from September 2009 to January 2011; Worldwide Chairman, Surgical Care Group from January 2009 to September 2009; Company Group Chairman and Worldwide Franchise Chairman for Ethicon, Inc., a subsidiary of the Company, from 2008 to January 2009; and held other various positions of increasing responsibility at the Company and its subsidiaries from 1988 to 2004. Defendant Gorsky knowingly, recklessly, or with gross negligence caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Gorsky the following compensation as an executive:

Year	Salary	Stock Awards	Option Awards	Non-Equity Incentive Plan Compensation	Change in Pension Value and Non-Qualified Deferred Compensation Earnings	All Other Compensation	Total
2019	$1,650,000	$9,956,365	$4,049,997	$3,690,971	$5,775,000	$243,444	$25,365,777
2018	$1,642,308	$10,319,463	$4,305,594	$3,570,497	-	$259,710	$20,097,572
2017	$1,600,000	$12,354,361	$5,054,398	$3,598,382	$6,959,144	$236,279	$29,802,564
2016	$1,600,000	$10,608,901	$4,118,398	$4,652,556	$5,663,771	$228,094	$26,871,720
2015	$1,613,462	$10,693,427	$4,562,998	$4,009,536	$2,714,268	$202,175	$23,795,866
2014	$1,500,000	$9,467,380	$4,168,139	$5,018,779	$4,606,142	$228,866	$24,989,306
2013	$1,453,846	$5,988,975	$2,669,999	$4,867,361	$1,739,000	$191,779	$16,910,960
2012	$1,087,188	$2,790,229	$1,482,631	$3,407,287	$2,050,000	$159,774	$10,977,109
2011	$847,692	$673,222	$1,081,161	$2,836,003	$1,316,000	$82,782	$6,836,860

Defendant Gorsky is a citizen of Pennsylvania.

24. Defendant Jennifer L. Taubert ("Taubert") is J&J's Executive Vice President, Worldwide Chairman, Pharmaceuticals and a Member of the Executive

Committee and has been since July 2018. Defendant Taubert was also J&J's Company Group Chairman, The Americas, Pharmaceuticals from 2015 to July 2018; Company Group Chairman, North America Pharmaceuticals from 2012 to 2015; and has held other various positions of increasing responsibility at the Company and its subsidiaries since joining the Company in 2005 as Worldwide Vice President, Johnson & Johnson Pharmaceutical Services. Defendant Taubert knowingly, recklessly, or with gross negligence caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Taubert the following compensation as an executive:

Year	Salary	Stock Awards	Option Awards	Non-Equity Incentive Plan Compensation	Change in Pension Value and Non-	All Other Compensation	Total
2019	$796,154	$2,625,279	$1,200,004	$1,179,065	$1,237,000	$59,798	$7,097,300

Defendant Taubert is a citizen of New Jersey.

25. Defendant Joaquin Duato ("Duato") is J&J's Vice Chairman of the Executive Committee and has been since July 2018. Defendant Duato was also J&J's Executive Vice President, Worldwide Chairman, Pharmaceuticals and a Member of the Executive Committee from April 2016 to July 2018; Worldwide Chairman, Pharmaceuticals from 2011 to April 2016; Company Group Chairman, Pharmaceuticals from 2009 to 2011; and has held other various positions of increasing responsibility at the Company and its subsidiaries since joining the Company in 1989. Defendant Duato knowingly, recklessly, or with gross negligence

caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Duato the following compensation as an executive:

Year	Salary	Stock Awards	Option Awards	Non-Equity Incentive Plan Compensation	Change in Pension Value and Non-	All Other Compensation	Total
2019	$969,615	$4,622,787	$1,974,005	$2,295,437	$3,469,000	$88,458	$13,419,302
2018	$934,046	$4,275,951	$1,892,999	$2,010,088	$79,000	$91,876	$9,283,960
2017	$897,254	$11,483,016	$1,650,003	$1,928,262	$3,329,047	$71,726	$19,359,308
2016	$875,000	$3,198,483	$1,260,002	$2,158,006	$2,535,760	$77,278	$10,104,529

Defendant Duato is a citizen of New Jersey.

26. Defendant Anne M. Mulcahy ("Mulcahy") is J&J's Lead Director and has been since December 2012 and a director and has been since October 2009. Defendant Mulcahy is a member of J&J's Audit Committee and has been since at least March 2013. Defendant Mulcahy knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Mulcahy the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	All Other Compensation	Total
2019	$155,000	$184,979	$20,000	$359,979
2018	$150,000	$184,940	$20,000	$354,940
2017	$145,000	$174,893	-	$319,893
2016	$140,000	$164,985	$20,000	$324,985
2015	$140,000	$154,899	$20,000	$314,899
2014	$140,000	$154,924	$20,000	$314,924
2013	$140,000	$144,989	-	$284,989
2012	$110,000	$144,913	-	$254,913
2011	$122,500	$99,974	-	$222,474

2010	$112,500	$99,942	-	$212,442
2009	$19,355	$60,640	-	$79,995

Defendant Mulcahy is a citizen of Connecticut.

27. Defendant Charles Prince ("Prince") is a J&J director and has been since February 2006. Defendant Prince is the Chair of J&J's Regulatory Compliance Committee and has been since at least March 2017. Defendant Prince knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Prince the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	All Other Compensation	Total
2019	$140,000	$184,979	$20,000	$344,979
2018	$135,000	$184,940	$20,000	$339,940
2017	$130,000	$174,893	$20,000	$324,893
2016	$130,000	$164,985	$20,000	$314,985
2015	$130,000	$154,899	$20,000	$304,899
2014	$130,000	$154,924	-	$284,924
2013	$130,000	$144,989	$20,524	$295,513
2012	$130,000	$144,913	$20,000	$294,913
2011	$137,500	$99,974	$20,000	$257,474
2010	$125,000	$99,942	-	$224,942
2009	$120,000	$99,978	-	$219,978

Defendant Prince is a citizen of Florida.

28. Defendant William D. Perez ("Perez") was a J&J director from June 2007 to April 2020. Defendant Perez was also a member of J&J's Audit Committee from at least March 2017 to at least March 2020, and also a member of the Public Policy Advisory Committee from at least March 2009 to at least March 2010.

Defendant Perez knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Perez the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	All Other Compensation	Total
2019	$140,000	$184,979	$20,000	$344,979
2018	$135,000	$184,940	$20,000	$339,940
2017	$130,000	$174,893	$20,000	$324,893
2016	$130,000	$164,985	$20,000	$314,985
2015	$130,000	$154,899	$20,000	$304,899
2014	$130,000	$154,924	-	$284,924
2013	$130,000	$144,989	$20,000	$294,989
2012	$130,000	$144,913	$20,000	$294,913
2011	$132,500	$99,974	$20,000	$252,474
2010	$120,000	$99,942	$20,000	$239,942
2009	$110,000	$99,978	$20,000	$229,978

Defendant Perez is a citizen of Florida.

29. Defendant Ian E. L. Davis ("I. Davis") is a J&J director and has been since July 2010. Defendant I. Davis is a member of J&J's Audit Committee and has been since at least March 2011, and a member of the Regulatory Compliance Committee and has been since at least March 2017. Defendant I. Davis was previously a member of J&J's Public Policy Advisory Committee from at least March 2011 to at least March 2012, and a member of the Science, Technology & Sustainability Committee from at least March 2013 to at least March 2016. Defendant I. Davis knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the

floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant I. Davis the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	Total
2019	$120,000	$184,979	$304,979
2018	$115,000	$184,940	$299,940
2017	$110,000	$174,893	$284,893
2016	$110,000	$164,985	$274,985
2015	$110,000	$154,899	$264,899
2014	$110,000	$154,924	$264,924
2013	$110,000	$144,989	$254,989
2012	$110,000	$144,913	$254,913
2011	$120,000	$99,974	$219,974
2010	$55,000	$59,580	$114,580

Upon information and belief, defendant I. Davis is a citizen of the United Kingdom.

30. Defendant Ronald A. Williams ("Williams") is a J&J director and has been since June 2011. Defendant Williams was previously the Chair of J&J's Regulatory Compliance Committee in at least March 2016, a member of that committee from at least March 2013 to at least March 2016, and a member of the Public Policy Advisory Committee in at least March 2012. Defendant Williams knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Williams the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	All Other Compensation	Total
2019	$140,000	$184,979	$10,000	$334,979
2018	$130,000	$174,893	$20,000	$324,893
2017	$130,000	$174,893	$20,000	$324,893
2016	$130,000	$164,985	$20,000	$314,985

2015	$125,003	$154,899	$20,000	$299,902
2014	$110,000	$154,924	$20,000	$284,924
2013	$110,000	$144,989	-	$254,989
2012	$110,000	$144,913	-	$254,913
2011	$60,000	$67,060	-	$127,060

Defendant Williams is a citizen of Florida.

31. Defendant A. Eugene Washington ("Washington") is a J&J director and has been since November 2012. Defendant Washington is a member of J&J's Science, Technology & Sustainability Committee and has been since at least March 2013, and was previously a member of the Regulatory Compliance Committee from at least March 2013 to March 2014. Defendant Washington knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Washington the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	All Other Compensation	Total
2019	$120,000	$184,979	$20,000	$324,979
2018	$115,000	$184,940	$20,000	$319,940
2017	$110,000	$174,893	-	$284,893
2016	$110,000	$164,985	$20,000	$294,985
2015	$110,000	$154,899	$20,000	$284,899
2014	$110,000	$154,924	$2,000	$266,924
2013	$110,000	$144,989	$5,772	$260,761
2012	$9,167	-	-	$9,167

Defendant Washington is a citizen of North Carolina.

32. Defendant Mark B. McClellan ("McClellan") is a J&J director and has been since October 2013. Defendant McClellan is a member of J&J's Regulatory

Compliance Committee and the Science, Technology & Sustainability Committee and has been since at least March 2014. Defendant McClellan knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant McClellan the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	Total
2019	$120,000	$184,979	$304,979
2018	$115,000	$184,940	$299,940
2017	$110,000	$174,893	$284,893
2016	$110,000	$164,985	$274,985
2015	$110,000	$154,899	$264,899
2014	$110,000	$154,924	$264,924
2013	$27,500	-	$27,500

Defendant McClellan is a citizen of North Carolina.

33. Defendant D. Scott Davis ("S. Davis") is a J&J director and has been since June 2014. Defendant S. Davis is the Chair of J&J's Audit Committee and has been since at least March 2016, and a member of that committee and has been since at least March 2015. Defendant S. Davis was previously a member of J&J's Regulatory Compliance Committee from at least March 2015 to at least March 2016. Defendant S. Davis knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant S. Davis the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	Total
2019	$145,000	$184,979	$329,979
2018	$140,000	$184,940	$324,940
2017	$135,000	$174,893	$309,893
2016	$135,000	$164,985	$299,985
2015	$128,750	$154,899	$283,649
2014	$58,366	-	$58,366

Upon information and belief, defendant S. Davis is a citizen of Georgia.

34. Defendant Mary C. Beckerle ("Beckerle") is a J&J director and has been since June 2015. Defendant Beckerle is the Chair of J&J's Science, Technology & Sustainability Committee and has been since at least March 2017, a member of that committee and has been since at least March 2016, and a member of the Regulatory Compliance Committee and has been since at least March 2017. Defendant Beckerle knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Beckerle the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	All Other Compensation	Total
2019	$140,000	$184,979	$20,000	$344,979
2018	$135,000	$184,940	$20,000	$339,940
2017	$130,000	$174,893	$20,000	$324,893
2016	$111,667	$164,985	$17,800	$294,452
2015	$64,167	-	-	$64,167

Defendant Beckerle is a citizen of Utah.

35. Defendant Mary S. Coleman ("Coleman") was a J&J director from September 2003 to April 2016. Defendant Coleman was a member of J&J's Audit Committee and the Science, Technology & Sustainability Committee from at least March 2009 to at least March 2016. Defendant Coleman knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Coleman the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	All Other Compensation	Total
2016	$36,666	$164,985	$20,000	$221,651
2015	$110,000	$154,899	$20,000	$284,899
2014	$110,000	$154,924	$20,000	$284,924
2013	$110,000	$144,989	$20,710	$275,699
2012	$110,000	$144,913	$20,000	$274,913
2011	$120,000	$99,974	$19,998	$239,972
2010	$110,000	$99,942	$19,998	$229,940
2009	$110,000	$99,978	$20,000	$229,978

Defendant Coleman is a citizen of Michigan.

36. Defendant James G. Cullen ("Cullen") was a J&J director from September 1995 to April 2015. Defendant Cullen was the Chair of J&J's Audit Committee from at least March 2009 to at least March 2015. Defendant Cullen knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Cullen the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	All Other Compensation	Total
2015	$45,000	$154,899	-	$199,899
2014	$135,000	$154,924	-	$289,924
2013	$135,000	$144,989	$20,000	$299,989
2012	$165,000	$144,913	-	$309,913
2011	$155,000	$99,974	$20,000	$274,974
2010	$130,000	$99,942	-	$229,942
2009	$130,000	$99,978	-	$229,978

Defendant Cullen is a citizen of New Jersey.

37. Defendant Leo F. Mullin ("Mullin") was a J&J director from July 1999 to April 2015. Defendant Mullin was a member of J&J's Audit Committee from at least March 2009 to March 2015; the Chair of the Regulatory Compliance Committee from April 2012 to at least March 2015; and the Chair of the Public Policy Advisory Committee from at least March 2009 to April 2012. Defendant Mullin knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Mullin the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	All Other Compensation	Total
2015	$43,333	$154,899	$20,000	$218,232
2014	$130,000	$154,924	-	$284,924
2013	$130,000	$144,989	$21,884	$296,873
2012	$130,000	$144,913	$16,666	$291,579
2011	$130,000	$99,974	$20,000	$249,974
2010	$120,000	$99,942	$20,000	$239,942
2009	$120,000	$99,978	$20,000	$239,978

Defendant Mullin is a citizen of Georgia.

38. Defendant Michael M. E. Johns ("Johns") was a J&J director from April 2005 to April 2014. Defendant Johns was a member of J&J's Science, Technology & Sustainability Committee from at least March 2009 to at least March 2014. Defendant Johns knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Johns the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	All Other Compensation	Total
2014	$36,667	$154,924	$20,000	$211,591
2013	$110,000	$144,989	$10,000	$264,989
2012	$110,000	$144,913	$20,000	$274,913
2011	$122,500	$99,974	$10,000	$232,474
2010	$112,500	$99,942	$10,000	$222,442
2009	$110,000	$99,978	$20,000	$229,978

Defendant Johns is a citizen of Georgia.

39. Defendant David Satcher ("Satcher") was a J&J director from April 2002 to April 2013. Defendant Satcher was a member of J&J's Public Policy Advisory Committee from at least March 2009 to April 2012; a member of the Regulatory Compliance Committee from April 2012 to at least March 2013; the Chair of the Science, Technology & Sustainability Committee from at least March 2009 to March 2012, and a member of that committee until at least March 2013. Defendant Satcher knowingly or recklessly caused or allowed the Company to engage in a false, deceptive, and misleading marketing campaign that opened the

floodgates of opioid use and abuse, and subjected the Company to billions of dollars in liability. J&J paid defendant Satcher the following compensation as a director:

Fiscal Year	Fees Earned or Paid in Cash	Stock Awards	All Other Compensation	Total
2013	$36,667	$144,989	$22,247	$203,903
2012	$130,000	$144,913	$10,000	$284,913
2011	$130,000	$99,974	$20,000	$249,974
2010	$120,000	$99,942	$20,000	$239,942
2009	$120,000	$99,978	$20,000	$239,978

Defendant Satcher is a citizen of Georgia.

40. The defendants identified in ¶¶23-25 are referred to herein as the "Officer Defendants." The defendants identified in ¶¶23, 26-39 are referred to herein as the "Director Defendants." Collectively, the defendants identified in ¶¶23-39 are referred to herein as the "Individual Defendants."

DUTIES OF THE INDIVIDUAL DEFENDANTS

Fiduciary Duties

41. By reason of their positions as officers and directors of the Company, each of the Individual Defendants owed and owe J&J and its stockholders fiduciary obligations of trust, loyalty, good faith, and due care, and were and are required to use their utmost ability to control and manage J&J in a fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of J&J and not in furtherance of their personal interest or benefit.

42. To discharge their duties, the officers and directors of J&J were required to exercise reasonable and prudent supervision over the management, policies, practices, and controls of the financial affairs of the Company. By virtue of such duties, the officers and directors of J&J were required to, among other things:

(a) ensure that the Company was operated in a diligent, honest, and prudent manner in compliance with all applicable laws, rules, and regulations;

(b) ensure that the Company complied with its legal obligations and requirements, and refrain from engaging in deceptive conduct;

(c) conduct the affairs of the Company in an efficient, business-like manner in compliance with all applicable laws, rules, and regulations so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock; and

(d) remain informed as to how J&J conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, make reasonable inquiry in connection therewith, and take steps to correct such conditions or practices and make such disclosures as necessary to comply with applicable laws.

J&J's Principles of Corporate Governance and Code of Business Conduct Impose Additional Responsibilities on the Defendants

43. The Individual Defendants, like all employees, directors, and officers of the Company, were required to comply with J&J's Principles of Corporate Governance (the "Corporate Governance Principles") and Code of Business Conduct (the "Code of Conduct"). The Individual Defendants were also required to comply with the Company's Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers (the "D&O Code of Conduct").[8] The Corporate Governance Principles state the following with respect to the responsibilities of the Board:

> **Responsibilities of the Board.** All Directors are elected annually by the shareholders as their representatives in providing oversight of the operation of the Company. The Directors select, oversee and monitor the performance of the senior management team, which is charged with the day-to-day conduct of the Company's business. The fundamental responsibility of the Directors is to exercise their business judgment on matters of critical and long-term significance to the Company in furtherance of what they reasonably believe to be in the best interest of the Company, and therefore its shareholders.

44. In addition to the duties described above, the Company must conduct its business in accordance with applicable laws and regulations. To that effect, both the Code of Conduct and the D&O Code of Conduct required the Company's officers and directors to comply with all laws, rules, and regulations, and the D&O Code of

[8] The D&O Code of Conduct refers to the Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers updated March 7, 2016.

Conduct further required the Individual Defendants to "use all reasonable efforts to oversee compliance by employees, other Directors and other Executive Officers with all applicable laws, rules and regulations." The Code of Conduct provided the following with respect to legal and regulatory compliance:

> We aspire to bring the highest standards and level of integrity to each of these business activities by:
>
> - Complying with the laws, standards and regulations that apply to our products and processes (such as quality regulations and standards);
> - Upholding ethical, scientific and clinical standards and complying with all laws and regulations in all research and development activities worldwide;
> - Ensuring the safety of patients and volunteers who take part in clinical trials, protecting their confidentiality and complying with data protection laws;
> - Complying with the laws and regulations that cover gaining marketing authorization to sell our products and interacting with regulators and other government officials;
> - Adhering to the applicable manufacturing, packaging, distribution and export laws and regulations for our industry and in the countries where we do business;
> - ***Following all laws and regulations regarding the promotion, marketing and sales of our products,*** including ensuring that what we say is truthful, not misleading, and is consistent with regulatory approvals for our products;
> - Complying with all laws relating to product quality and safety, consistently monitoring the safety, quality and performance of our products and complying with all requirements for reporting adverse events and product quality complaints.

(Emphasis Supplied).

45. Thus, J&J's Principles of Corporate Governance and its Codes of Conduct made clear that the Individual Defendants were tasked with taking all necessary and appropriate steps to make sure that the Company, including its highest management, complied with all applicable internal policies and fair business practices.

Breaches of Duties

46. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as officers and directors of J&J, the absence of good faith on their part, and a reckless disregard for their duties to the Company that the Individual Defendants were aware or reckless in not being aware posed a risk of serious injury to the Company.

47. The Individual Defendants breached their duty of loyalty and good faith by allowing defendants to cause, or by themselves causing, the Company to engage in deceptive practices with respect to its marketing and promotion of opioids. These improper practices caused J&J to incur substantial damage.

48. The Individual Defendants, because of their positions of control and authority as officers and/or directors of J&J, were able to and did, directly or indirectly, exercise control over the wrongful acts complained of herein. The Individual Defendants also failed to prevent the other Individual Defendants from taking such illegal actions. As a result, and in addition to the damage the Company

has already incurred, J&J has expended, and will continue to expend, significant sums of money.

CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION

49. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with and conspired with one another in furtherance of their common plan or design. In addition to the wrongful conduct herein alleged as giving rise to primary liability, the Individual Defendants further aided and abetted and/or assisted each other in breaching their respective duties.

50. During all times relevant hereto, the Individual Defendants, collectively and individually, initiated a course of conduct that was designed to and did: (i) deceive the public as to the benefits of opioids and their associated risks; and (ii) enhance the Individual Defendants' executive and directorial positions at J&J and the profits, power, and prestige that the Individual Defendants enjoyed as a result of holding these positions. In furtherance of this plan, conspiracy, and course of conduct, the Individual Defendants, collectively and individually, took the actions set forth herein.

51. The Individual Defendants engaged in a conspiracy, common enterprise, and/or common course of conduct. During this time, the Individual

Defendants caused the Company to disseminate misleading information about the benefits and risks associated with opioids.

52. The purpose and effect of the Individual Defendants' conspiracy, common enterprise, and/or common course of conduct was, among other things, to disguise the Individual Defendants' violations of law, breaches of fiduciary duty, and unjust enrichment; and to conceal adverse information concerning the Company's operations and future business prospects.

53. Because the actions described herein occurred under the authority of the Board, each of the Individual Defendants was a direct, necessary, and substantial participant in the conspiracy, common enterprise, and/or common course of conduct complained of herein.

54. Each of the Individual Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commission of the wrongdoing complained of herein, each Individual Defendant acted with knowledge of the primary wrongdoing, substantially assisted in the accomplishment of that wrongdoing, and was aware of his or her overall contribution to and furtherance of the wrongdoing.

FACTUAL BACKGROUND

55. J&J and its subsidiaries manufacture, sell, and distribute a range of pharmaceutical drugs, including opioids. Among other opioid products, the

Company promotes, distributes, and sells DURAGESIC, a transdermal patch made out of the API fentanyl, a synthetic opioid that is 100 times stronger than morphine and fifty times stronger than heroin. Prior to 2009, DURAGESIC accounted for at least $1 billion in annual sales. Until January 2015, the Company also developed, marketed, and sold NUCYNTA and NUCYNTA ER—tablets made out of the API, tapentadol. Together, NUCYNTA and NUCYNTA ER accounted for $172 million in sales in 2014.

56. Opioids, including DURAGESIC, NUCYNTA, and NUCYNTA ER, are categorized as "Schedule II Controlled Substances" due to their high potential for abuse and potential to cause severe psychological and physiological dependence. Most patients receiving more than a few weeks of opioid therapy will experience withdrawal symptoms if opioid use is delayed or discontinued—including severe anxiety, nausea, headaches, tremors, delirium, and pain—which are often prolonged. When using opioids continuously, patients grow tolerant to their analgesic effects (i.e., to relief of pain) and require progressively higher doses, which increases the risks of withdrawal, addiction, and overdose.

57. Recognizing these dangers, the medical community historically prescribed opioids only for short-term acute pain—where brief use limited the need for escalating doses and the risk of addiction was minimal—and for terminal illnesses and end-of-life care. As a result, the market for prescription opioids was

sharply constrained. Not so today. Opioids are now the most prescribed class of drugs in the U.S.

58. The roots of the opioid epidemic date back to the mid-1990s, when Purdue developed the opioid OxyContin. In 1994, the same year Purdue sought approval from the FDA to sell OxyContin, J&J, through its subsidiary, Tasmanian Alkaloids, established a research project for the development of a high thebaine poppy to meet the anticipated demand for OxyContin. This project resulted in the development of the "Norman" poppy, which coincided with the release of a slow release formulation of oxycodone in the U.S.[9] J&J internally described the new poppy as "a transformational technology." The Norman poppy enabled the growth of oxycodone.

59. At the time, oxycodone was perceived as less potent than morphine, largely because it was most commonly prescribed as Percocet, a relatively weak oxycodone-acetaminophen combination pill. Oxycodone was sometimes mistakenly called "oxycodeine," which contributed to the perception of relatively lower potency, as codeine is weaker than morphine. Purdue took advantage of these

[9] A.J. Fist, *The Tasmanian Poppy Industry: A Case Study of the Application of Science and Technology*, Tasmanian Alkaloids Pty. Ltd., Westbury, Tasmania.

misconceptions, marketing OxyContin as lower risk than traditional immediate release narcotics.[10]

60. Purdue sought to expand the market for OxyContin by changing prescribers' perception of opioids in order to permit and encourage the use of opioids long-term for widespread chronic conditions like back pain, migraines, and arthritis. As part of its strategy, in addition to promoting its OxyContin product as lower-risk than traditional opioids, Purdue promoted opioids in general as safe, effective, and appropriate for long-term use for routine pain conditions, and misrepresented the risk of addiction for pain patients as modest, manageable, and outweighed by the benefits of opioid use. Purdue spent tens of millions of dollars every year to support its promotional efforts. Purdue was successful in creating a market for the use of opioids for a range of common aches and pains.

[10] Purdue acknowledged using this to its advantage when it later pled guilty to criminal charges of "misbranding" in 2007, admitting that it was "well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine" and "did not want to do anything 'to make physicians think that oxycodone was stronger or equal to morphine' or to 'take any steps ... that would affect the unique position that OxyContin'" held among physicians. Christopher Glazek, *The Secretive Family Making Billions from the Opioid Crisis*, Esquire (Oct. 16, 2017), http://www.esquire.com/news-politics/a12775932/sackler-family-oxycontin/.

J&J HAS A HISTORY OF MISLEADINGLY MARKETING ITS PHARMACEUTICALS

J&J's Deceptive Marketing of Topamax

61. J&J's directors and officers—including the defendants—were on notice before and during its misleading marketing of opioid products that J&J has a long history of deceptive marketing tactics and known systemic internal control issues related thereto.

62. For example, J&J subsidiaries Ortho-McNeil Pharmaceutical LLC and Ortho-McNeil-Janssen Pharmaceuticals Inc. (combined later into Janssen) engaged in illegal marketing of the Company's epilepsy drug, TOPAMAX®, for off-label uses, despite serious birth defects, including clef lip, associated with the drug's use. The subsidiaries pled guilty to violating the Federal Food, Drug, and Cosmetic Act ("FDCA") 21 U.S.C. §§331(a), 333(a)(1), and 352(f). J&J's Board approved the plea.

63. Among the accusations in these cases, the Company's subsidiaries had engaged in illegal payments to physicians to promote Topamax. Sales representatives pushed Topamax by downplaying the birth defect risk.

64. J&J paid $81 million in criminal and civil penalties to resolve qui tam and False Claims Act cases *U.S. ex rel. Maher, et al. v. Ortho-McNeil Pharmaceutical*, No. 03-11445-WGY (D. Mass. 2010), and *U.S. ex rel. Spivack v.*

Johnson & Johnson and Ortho- McNeil Pharmaceutical, Inc., No. 04-11886-WGY (D. Mass. 2010).

65. Moreover, as the 2020 Report itself acknowledges, J&J agreed to a term of probation under a 2010 Corporate Integrity Agreement ("CIA") that required additional oversight duties to be put in place to prevent illegal marketing practices. Exhibit H at 44.

J&J's Illegal Marketing of Risperdal

66. Defendants' implemented policies as part of the 2010 CIA were ineffectual. J&J continued to face significant liability for its improper marketing techniques. This time, with a majority of the current Board in place, the Company came under serious fire related to Janssen's illegal sale of RISPERDAL®, a powerful antipsychotic drug used to treat schizophrenia, bipolar disorder, and irritability caused by autism.

67. Risperdal has significant side effects, including gynecomastia, a hormonal disorder that causes higher-than-normal estrogen levels in boys and men, causing them to grow female breasts. J&J engaged in a well-financed campaign to undercut this side effect by training sales representatives to pitch Risperdal to doctors while downplaying its side-effects, supporting supposedly "independent" articles in medical journals that endorsed off-label uses and rewarding doctors for prescribing for off-label uses.

68. J&J and Janssen's illicit sales and marketing of Risperdal exposed the Company to substantial liability in the form of a criminal action, qui tam whistleblower actions, tens of thousands of personal injury lawsuits, and numerous securities class actions. A majority of the members of the Board—including defendants Gorsky, Coleman, Cullen, I. Davis, Johns, McClellan, Mulcahy, Mullin, Perez, Prince, Washington, and Williams—were aware of this liability because, in November 2013, those defendants approved J&J's guilty plea in *USA v. Janssen Pharmaceuticals, Inc., et al.*, No. 2:13-cr-000605 (E.D. Pa. 2013) for off-label marketing violations of 21 U.S.C. §§331(a), 333(a)(1) and 352(f)(1) of the False Claims Act. The 2013 guilty plea came with a $2.2 billion price tag in fines and settlements for the deceptive marketing of Risperdal.

69. Further, as the 2020 Report acknowledges, J&J was forced to enter another five-year CIA with the U.S. Office of the Inspector General in October 2013. Exhibit H at 44. The CIA mandated that J&J's fiduciaries "undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements," including certain policies to enhance risk assessment and mitigation for the selling, detailing, marketing, advertising, promoting, and branding of the Company's drugs.

70. Defendants were also aware of the $335 million global settlement of a qui tam case, *U.S. ex rel. Lisitza, et al. v. Johnson & Johnson, et al.*, Case No. 1:07-

cv-10288-RGS (D. Mass. 2011), alleging that Janssen engaged in illegal kickbacks to Omnicare, Inc. to induce prescription of Risperdal in Omnicare's nursing facilities.

THE COMPANY ENGAGED IN A DECEPTIVE MARKETING SCHEME TO UNLAWFULLY INCREASE ITS REVENUE FROM OPIOIDS

71. J&J and other opioid developers took advantage of the market created by Purdue's aggressive promotion of OxyContin by bringing new opioids to market and expanding the use of their existing opioid products. To develop the market, the Opioid Manufacturers engaged in widespread deceptive marketing campaigns designed to convince healthcare providers both that the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven. The result has been catastrophic. The United States is now awash in opioids. According to the CDC, the nation has been swept up in an opioid-induced "public health epidemic."

72. As detailed below, J&J played a major role in causing the opioid epidemic. J&J not only participated in this deceptive opioid promotion scheme, but, through its subsidiaries Noramco and Tasmanian Alkaloids, the Company also supplied opium-based ingredients to other opioid manufacturers. Thus, J&J profited not only from sales of its own opioid products, but also from the sale of its API to other manufacturers, and therefore was driven to develop the market as much as possible.

The Opioid Manufacturers' Deceptive Opioid Promotion Scheme

73. The Opioid Manufacturers spent hundreds of millions of dollars on promotional activities and materials, including advertising and websites that falsely denied or trivialized the risk of addiction and overstated the benefits of opioids. In particular, the Opioid Manufacturers' deceptive marketing included: (i) misrepresenting that opioids improve function; (ii) concealing the link between long-term use of opioids and addiction; (iii) misrepresenting that addiction risk can be managed; (iv) masking the signs of addiction by calling them "pseudoaddiction"; (v) falsely claiming withdrawal is easily managed; (vi) misrepresenting or omitting the greater dangers from higher doses of opioids; and (vii) minimizing the adverse effects of opioids and overstating the risks of nonsteroidal anti-inflammatory drugs ("NSAIDs").

74. ***First***, to convince medical professionals to prescribe more opioids to a broader range of patients, the Opioid Manufacturers touted the purported benefits of long-term opioid use, and claimed—without evidence—that long-term opioid use would help patients resume their lives and jobs. These claims encouraged doctors to continue opioid therapy in the belief that failure to improve pain, function, or quality of life could be overcome by increasing doses or prescribing supplemental short-acting opioids to take on an as-needed basis for breakthrough pain.

75. The Opioid Manufacturers' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. According to the CDC's Guideline for Prescribing Opioids for Chronic Pain (the "CDC Guideline"), there is "insufficient evidence to determine long-term benefits of opioid therapy for chronic pain." In fact, the CDC has found that there is "[n]o evidence show[ing] a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)." The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."[11]

76. Not only is there no evidence of improvement in long-term functioning, but the available evidence indicates that other treatments are more or equally effective and less harmful than long-term opioid use. For instance, a 2006 study-of-studies found that "[f]or functional outcomes ... other analgesics were significantly more effective than were opioids."[12] Studies of the use of opioids in chronic

[11] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

[12] Andrea D. Furlan, et al., *Opioids for Chronic Noncancer Pain: a Meta-Analysis of Effectiveness and Side Effects*, 174(11) Can. Med. Ass'n J. 1589-94 (2006). This

conditions for which they are now commonly prescribed corroborate this conclusion. These studies have consistently shown that patients using opioids long-term experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures. As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[13]

77. ***Second***, the Opioid Manufacturers sought to convince prescribers and patients that opioids are safe by misrepresenting the risk of addiction from chronic opioid therapy. The Opioid Manufacturers brazenly maintained that the risk of addiction for patients who take opioids long-term was low and omitted the risk of addiction and abuse from the list of adverse outcomes associated with chronic opioid use, even though the frequency and magnitude of the risk compelled disclosure. The Opioid Manufacturers also undermined evidence that opioids are addictive by representing that the risk of addiction is limited to high-risk patients. There was no

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study revealed that efficacy studies do not typically include data on opioid addiction, such that, if anything, the data overstate effectiveness.

[13] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009).

scientific evidence to support those claims, and in fact, the available research contradicted them. A 2015 literature survey found that while ranges of "problematic use" of opioids ranged from 1% to 81%, abuse averaged between 21% and 29%, and addiction between 8% and 12%.[14]

78. In addition to making outright misrepresentations about the risk of opioid addiction generally, the Opioid Manufacturers falsely represented that their respective opioid drugs were safer, and less prone to abuse and addiction than other opioids. For instance, Actavis, Endo, Janssen, and Purdue each promoted their drugs as having "steady-state" properties—meaning that their drugs caused less of a rush or a feeling of euphoria, which can trigger abuse and addiction—and therefore were less likely to be abused or cause addiction.

79. ***Third***, to encourage physicians to prescribe more opioids, the Opioid Manufacturers repeatedly promoted the concept of "pseudoaddiction." The Opioid Manufacturers told prescribers that classic signs of addiction, such as asking for increasingly higher doses of opioids or seeking early refills, actually reflected undertreated pain that should be addressed with heavier doses of opioids. The Opioid Manufacturers' also promoted "pseudoaddiction" through unbranded promotional materials funneled through third parties. Their unbranded marketing

[14] Kevin Vowels, et al., *Rates of Opioid Misuse, Abuse, and Addiction in Chronic Pain: a Systematic Review and Data Synthesis*, 156 PAIN 569-76 (April 2015).

campaigns frequently focused on heightening awareness of the undertreatment of pain and its consequences. Their marketing materials repeatedly represented that purportedly overblown worries about addiction cause pain to be under-treated and opioids to be overregulated and underprescribed.

80. The Opioid Manufacturers' claims of "pseudoaddiction" were not substantiated by scientific evidence. In fact, the CDC Guideline for prescribing opioids for chronic pain rejects the concept of pseudoaddiction. To the contrary, the CDC Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment ... are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

81. ***Fourth***, the Opioid Manufacturers misrepresented that addiction risk can be avoided or managed. The Opioid Manufacturers told prescribers that to the extent there is a risk of opioid addiction, doctors can avoid or manage that risk by using screening tools and questionnaires. The Opioid Manufacturers advised doctors that they could use these tools to identify patients with higher addiction risks and closely monitor patients at greater risk of addiction.

82. These claims were misleading for a number of reasons. There is no reliable scientific evidence that high-risk or addicted patients can take opioids long-

term without triggering addiction, even with enhanced monitoring and precautions. Nor is there reliable scientific evidence that patients without these red flags are necessarily free of addiction risk. And, there is no reliable scientific evidence that screening works to accurately predict risk or reduce rates of addiction. In fact, an Evidence Report by the Agency for Healthcare Research and Quality, which "systematically review[ed] the current evidence on long-term opioid therapy for chronic pain" identified "[n]o study" that had "evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse-deterrent formulations on outcomes related to overdose, addiction, abuse or misuse."[15]

83. The CDC Guideline confirms the falsity of the Opioid Manufacturers' claims about the utility of patient screening and management strategies in managing addiction risk. The CDC Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools or patient contracts—"for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognized that available risk screening tools "show

[15] *The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain*, Agency for Healthcare Res. & Quality (September 19, 2014).

insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counseled that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

84. ***Fifth***, to encourage prescribers and patients to use chronic opioid therapy, the Opioid Manufacturers understated the difficulty of withdrawing from opioids and claimed opioid withdrawal is simply managed. The Opioid Manufacturers routinely represented that while patients may become "physically" dependent on opioids, this dependence can be addressed by gradually tapering patients' doses to avoid the adverse effects of withdrawal. They failed to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—effects that also make it less likely that patients will be able to stop using the drugs.

85. In reality, withdrawal is prevalent in patients after more than a few weeks of therapy, and common symptoms of withdrawal include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, and pain. Some symptoms may persist for months, or even years, after a complete withdrawal from opioids, depending on how long opioids were used. Withdrawal symptoms trigger a feedback loop that drives patients to seek opioids, contributing to addiction.

86. ***Sixth***, the Opioid Manufacturers falsely represented that opioid doses can be increased without limit or greater risks. The Opioid Manufacturers claimed patients and prescribers could increase doses of opioids indefinitely without added risk, even when pain was not decreasing or when doses had reached levels that were "frighteningly high," suggesting that patients would eventually reach a stable, effective dose. The Opioid Manufacturers also omitted warnings of increased adverse effects that occur at higher doses, and misleadingly suggested that there was no greater risk to higher dose opioid therapy.

87. These claims are false and contrary to scientific evidence. Patients receiving high doses of opioids (e.g., doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.

88. The FDA has itself acknowledged that available data suggests a relationship between increased doses and the risk of adverse effects. Moreover, it is harder for patients to terminate use of higher-dose opioids without severe withdrawal

effects, which contributes to a cycle of continued use, even when the drugs provide no pain relief and are causing harm—the signs of addiction. The CDC Guideline likewise concludes that the "[b]enefits of high-dose opioids for chronic pain are not established" while there is "an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent." Accordingly, the CDC advises doctors to "avoid increasing dosage" above 90 mg MED per day.[16]

89. ***Seventh***, the Opioid Manufacturers deceptively omitted or minimized adverse effects of opioids and overstated the risks of alternative forms of pain treatment. Materials the Opioid Manufacturers produced, sponsored, or controlled omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or NSAIDs. None of these claims were corroborated by scientific evidence. In fact, several studies have shown that ibuprofen and acetaminophen taken together are better than opioids at relieving pain such as dental pain, low back pain, and moderate acute traumatic pain.[17]

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[16] Thomas R. Frieden and Debra Houry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline*, at 1503, NEJM (Apr. 21, 2016).

[17] Donald Teater, M.D., *Evidence for the Efficacy of Pain Medication*, National Safety Council (October 2014).

90. The Opioid Manufacturers' promotional materials also routinely ignored other risks associated with opioids, such as hyperalgesia, a known serious risk associated with chronic opioid analgesic therapy, in which the patient becomes more sensitive to pain over time; hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (conditions that often accompany chronic pain symptoms).

91. The Opioid Manufacturers' misrepresentations made healthcare providers more comfortable prescribing opioids to their patients and patients more comfortable starting chronic opioid therapy. These misrepresentations were especially insidious because the Opioid Manufacturers aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Moreover, these misrepresentations allowed doctors to believe opioid addiction was really "pseudoaddiction" and a sign patients required more opioids.

92. The Opioid Manufacturers' false and misleading claims had the effect of shifting the balance of opioids' risks and purported benefits. The CDC reports that the quantity of opioids dispensed per capita tripled from 1999 to 2015. While

opioid prescriptions exploded over the past two decades, the use of NSAIDs has dramatically declined. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.[18]

93. The dramatic increase in opioid prescriptions to treat common chronic pain conditions caused a substantial rise in opioid overdose deaths and opioid addiction treatment admissions. Nationally, from 1999 through 2016, more than 350,000 people in the U.S. died from an overdose involving opioids. Over 200,000 of those deaths involved patients who were prescribed opioids to treat pain. In 2017, more than 70,000 people died of drug overdoses, approximately two-thirds of those deaths were linked to opioids. According to the CDC, opioids have created a "public health epidemic."

J&J's Role in the Opioid Promotion Scheme

94. While the Opioid Manufacturer's deceptive marketing scheme caused devastating damage throughout the U.S., J&J profited handsomely from this unlawful scheme. Through its former subsidiaries, Tasmanian Alkaloids and Noramco, the Company supplied opium-based ingredients to a number of

[18] Matthew Daubresse, et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States*, 2000-2010, 51(10) Med. Care 870 (2013).

manufacturers for a range of drugs. Noramco and Tasmanian Alkaloids were the primary suppliers of the APIs for several opioid manufacturers. Eighty percent of Noramco's sales were with all seven of the top U.S. generic pharmaceutical manufacturers. Noramco and Tasmanian Alkaloids supplied opium-based ingredients—including Oxycodone, the API used in OxyContin, Percocet, and Roxicodone; Hydrocodone, the API used in Vicodin and Lortab; and Morphine, the API used in MS Contin and Embeda—to Teva, Endo, Purdue, Rhodes, Mallinckrodt, Actavis, Amneal, and KVK-Tech, among other manufacturers. Because Noramco and Tasmanian Alkaloids were the primary suppliers of the APIs for these opioid manufacturers, Janssen and J&J profited from the growth of both unbranded and branded opioids and was driven to develop the market as much as possible.

95. In 1997, after seeing the success that Purdue had in marketing OxyContin for chronic noncancer pain, J&J, through Janssen, relaunched its fentanyl-based DURAGESIC patch for the chronic noncancer market as well. J&J spent millions of dollars to promote DURAGESIC and its other branded opioids, NUCYNTA and NUCYNTA ER, and destigmatize and normalize the long-term use of opioids for chronic nonmalignant pain. Using multipronged marketing strategies that targeted physicians, other prescribers, and the general public through websites, print advertisements, and educational materials and events, the Company promoted both its own products and opioids in general as safe, effective, and appropriate for

the long-term treatment of routine pain conditions. To create the appearance of objectivity, J&J obscured its involvement in certain of its marketing activities by collaborating with and funding various "front groups," which wrote and disseminated favorable education materials and opioid treatment guidelines supporting opioid therapy for chronic pain.

96. A key component of the Company's marketing campaign was its sales representatives. The Company, through Janssen, aggressively targeted physicians and other high-volume prescribers by having its sales representatives visit these medical professionals to deliver favorable sales messages and educational materials supporting opioid therapy for chronic pain. J&J sales representatives falsely told prescribers that opioids would increase patients' ability to function and improve their quality of life by helping them become more physically active and return to work.

97. These sales representatives also falsely portrayed the Company's products as safer than other opioids. In particular, J&J sales representatives told prescribers that NUCYNTA and NUCYNTA ER were "unlike traditional opioids" and had "non-opioid" properties, implying that the risks of addiction and other adverse outcomes associated with opioids were not applicable to NUCYNTA and NUCYNTA ER. In truth, however, as set out in NUCYNTA's FDA mandated label, NUCYNTA "contains tapentadol, an opioid agonist and Schedule II substance with abuse liability similar to other opioid agonists, legal or illicit." In addition, J&J sales

representatives assured prescribers that NUCYNTA's unique properties eliminated the risk of addiction associated with the drug. In particular, the Company's sales representatives told prescribers that J&J's drugs were "steady state," implying that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.

98. The Company trained its sales representatives to perpetuate these falsehoods. A June 2009 NUCYNTA Training module warned Janssen's sales force that physicians are reluctant to prescribe controlled substances like NUCYNTA, but falsely assured this reluctance is unfounded because "the risks ... are much smaller than commonly believed." The Company also trained its sales representatives to downplay the risk and impact of addiction by falsely representing that withdrawal from opioids was not an issue. A Janssen PowerPoint presentation used for training its sales representatives titled "Selling Nucynta ER" indicates that the "low incidence of withdrawal symptoms" is a "core message" for its sales force. This false message was repeated in numerous Janssen training materials between 2009 and 2011.[19]

[19] The studies supporting this claim did not describe withdrawal symptoms in patients taking NUCYNTA ER beyond ninety days or at high doses and would therefore not be representative of withdrawal symptoms in the chronic pain population. Patients on opioid therapy long-term and at high doses will have a harder time discontinuing the drugs and are more likely to experience withdrawal symptoms. In addition, in claiming a low rate of withdrawal symptoms, Janssen relied upon a study that only began tracking withdrawal symptoms in patients two to four days after discontinuing opioid use, when Janssen knew or should have known that these symptoms peak earlier than that for most patients. Relying on data

99. The Company, through Janssen, also published misleading content online promoting the use of opioids generally. For example, Janssen's website for DURAGESIC included a section addressing "Your Right to Pain Relief" and a hypothetical patient's fear that "I'm afraid I'll become a drug addict." The website's response: "[a]ddiction is relatively rare when patients take opioids appropriately." Janssen also published a patient guide titled "Patient Booklet Answers to Your Questions – Duragesic," which reiterated that "[a]ddiction is relatively rare when patients take opioids appropriately."

100. The unbranded J&J website, PrescribeResponsibly.com, contained similar misrepresentations about opioids. This website stated that concerns about opioid addiction were "overestimated" and that "true addiction occurs only in a small percentage of patients." The website also promoted the Company's messaging that the solution to "pseudoaddiction" was to prescribe more opioids.

101. To avoid regulatory constraints and give its efforts an appearance of independence and objectivity, J&J obscured its involvement in certain of its marketing activities by collaborating with patient advocacy organizations, such as

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after that initial window painted a misleading picture of the likelihood and severity of withdrawal associated with chronic opioid therapy. Janssen also knew or should have known that the patients involved in the study were not on the drug long enough to develop rates of withdrawal symptoms comparable to rates of withdrawal suffered by patients who use opioids for chronic pain—the use for which Janssen promoted NUCYNTA ER.

the American Pain Foundation ("APF"), American Academy of Pain Medicine ("AAPM"), and American Society for Pain Management Nursing ("ASPMN"), to release misleading information about opioids. J&J provided funding to these groups and exercised significant influence over the educational programs and written materials they disseminated.

102. For instance, through Janssen, the Company sponsored and worked with the AAPM and the American Geriatrics Society ("AGS") to create a patient education guide titled "Finding Relief: Pain Management for Older Adults (2009)." The guide is rife with deceptive content about opioids. Among other misrepresentations, the guide claimed that long-term opioid use improves functioning. Using a myth/fact structure, the guide stated as "a fact" that "opioids may make it *easier* for people to live normally." The guide listed expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and stated that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

103. The guide also downplayed the addictive nature of opioids and suggested that as long as a prescription is given, opioid abuse was not an issue. Using the same fact/myth structure, the guide described the claim that opioids are

addictive as a "myth," and asserted as "fact" that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain."

104. Additionally, the guide misrepresented that increased doses of opioids posed no significant additional risks, listing dose limitations as "disadvantages" of other pain medicines but omitting any discussion of risks of increased doses from opioids. The guide falsely claimed that it is a "myth" that "opioid doses have to get bigger over time."

105. In conjunction with the APF, AAPM, and ASPMN, Janssen also sponsored, developed, and approved misleading content about opioids on the website "Let's Talk Pain." Featuring an interview claiming that opioids allowed a patient to "continue to function," this website misrepresented that the use of opioids for the treatment of chronic pain would lead patients to regain functionality. The website also downplayed the risk of addiction from opioids, stating that "the stigma of drug addiction and abuse" associated with the use of opioids stemmed from a "lack of understanding about addiction." Let's Talk Pain also perpetuated the concept of pseudoaddiction, associating patient behaviors such as "drug seeking," "clock watching," and "even illicit drug use or deception" with undertreated pain which could be resolved with "effective pain management."

106. J&J also engaged in other promotional projects with and through APF. For example, J&J provided grants to APF to distribute the publication *Exit Wounds*

to veterans. *Exit Wounds* deceptively portrayed the risks, benefits, and superiority of opioids for the treatment of chronic pain. The publication taught that opioid medications "*increase* your level of functioning" and omitted warnings of the risk of interactions between opioids and benzodiazepines,[20] which would increase fatality risk.

107. The Company also used medical education events, including speakers bureau sessions and continuing medical education ("CME") opportunities as promotional endeavors to increase the market for opioids through misleading messaging. For instance, J&J created and funded the National Pain Education Council ("NPEC"), whose purpose was to provide CME related to pain and opioids to primary care physicians, pain specialists, oncologists, residents, nurses, and pharmacists. In the Company's 2003 Business Plan Summary for DURAGESIC, J&J described NPEC as serving "to benefit not only DURAGESIC but also all future Janssen pain products." CME materials for the Company's NPEC program disseminated false and misleading statements regarding opioids and pain management.

108. J&J, through Janssen, also contracted with AGS to produce a CME promoting the 2009 guidelines for the "Pharmacological Management of Persistent

[20] Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder.

Pain in Older Persons." These guidelines falsely claimed that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." The study supporting this assertion does not analyze addiction rates by age and addiction remains a significant risk for elderly patients. Janssen was aware of the AGS guidelines' content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion.

109. The Company was repeatedly notified that its opioid marketing, in its multitude of forms, was false, deceptive, and misleading. In 1998, the FDA found three different convention posters J&J used to promote DURAGESIC to contain marketing messages that were "false and misleading" for numerous reasons, including using misleading comparative efficacy claims without substantial evidence, taking data out of context to deliver misleadingly incomplete impressions, promoting unapproved uses, emphasizing the "chronic pain" indications without the limitations and restrictions, and deceptively minimizing risks and safety issues.

110. In 2001, J&J's own hired scientific advisory board advised the Company that many of the primary marketing messages it used to promote opioids generally, and DURAGESIC specifically, were misleading and should not be disseminated. In particular, the Company's scientific advisory board advised J&J not to market opioids, including fentanyl-based DURAGESIC, using messages

related to abuse or with claims about supposedly low abuse potential. The scientific advisory board noted that no data existed that could support these claims, that the data the Company pointed to (Drug Abuse Warning Network ("DAWN") data) was incapable of supporting these claims, that aggressively marketing OxyContin on this same basis was what had gotten Purdue "in trouble," that minimizing the risk of abuse of DURAGESIC was "dangerous" due to its lethal nature, and that an increase of DURAGESIC sales would cause an increase in abuse of the drug. The scientific advisory board warned the Company: "Do not include the abuse message. Do not sell opioids on the abuse issue."

111. Substantiating the advice of J&J's scientific advisors, in 2004, the FDA sent the Company a letter warning that a professional file card that J&J used to promote DURAGESIC contained "false or misleading claims about the abuse potential and other risks of [Duragesic], and include[d] unsubstantiated effectiveness claims for Duragesic." The FDA found that the DURAGESIC file card misbranded the drug by "suggesting that Duragesic has a lower potential for abuse compared to other opioid products," and "the file card could encourage the unsafe use of the drug, potentially resulting in serious or life-threatening hypoventilation." The FDA noted that J&J's suggestion that DURAGESIC was "less abused than other opioid drugs" was "false or misleading" because: (i) the FDA was "not aware of substantial evidence or substantial clinical experience to support this comparative claim"; and

(ii) "DAWN is not a clinical database" and "DAWN data cannot provide the basis for a valid comparison" among opioid products. The FDA concluded that the Company's DURAGESIC file card made "false or misleading safety claims and unsubstantiated effectiveness claims for Duragesic" and "thus misbrand[ed] Duragesic in violation of the Act (21 U.S.C. § 352(a))." The FDA advised J&J to "immediately cease the dissemination of promotional materials for Duragesic the same as or similar to those described" in the 2004 letter. The FDA further cautioned that the "violations discussed" in the letter did not "necessarily constitute an exhaustive list" and warned that it was J&J's responsibility to "ensure that [its] promotional materials for Duragesic comply with each applicable requirement of the Act and FDA implementing regulations."

112. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of DURAGESIC and its generic competitor, manufactured by Mylan N.V. The advisory noted that the FDA had been "'examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch'" and noted the possibility "that patients and physicians might be unaware of the risks" of using the fentanyl transdermal patch, which is a potent opioid analgesic approved only for chronic pain in opioid-tolerant patients that could not be treated by other drugs. Despite these warnings, J&J's deceptive marketing and sales of opioids continued.

J&J'S UNLAWFUL CONDUCT HAS SUBJECTED IT TO NUMEROUS LAWSUITS AND GOVERNMENTAL INVESTIGATIONS

113. The Company's deceptive marketing and promotion of opioids has subject J&J to numerous lawsuits and regulatory investigations. Since 2014, J&J and Janssen have been named as defendants in more than 2,500 lawsuits brought by various state and local governments related to the marketing of opioids. Additionally, over 2,200 federal cases have been coordinated in a MDL pending in the U.S. District Court for the Northern District of Ohio.

114. The Company and Janssen have also received subpoenas or requests for information related to its opioid marketing practices from at least thirteen state attorneys general. In September 2017, attorneys general from a coalition of states who are investigating the distribution of prescription opioid pain medication sent the Company requests for documents and information. J&J and Janssen also received requests for information from the ranking minority member of the United States Senate Committee on Homeland Security and Governmental Affairs regarding the sales, marketing, and educational strategies related to the promotion of opioid use.

115. On June 18, 2018, a New York state court rejected motions to dismiss brought by J&J and other defendants, finding sufficient factual allegations to support causes of action for violations of New York's consumer fraud and false advertising laws, as well as public nuisance, negligence, fraud and other claims. In doing so, the New York court stated:

> The plaintiffs allege the manufacturer defendants employed assiduously crafted, multi-pronged marketing strategies that targeted the general public through websites, print advertisements, and educational materials and publications as part of their respective campaigns to change the perception of the risks associated with prescription opioids and to de-stigmatize and normalize the long-term use of opioids for chronic nonmalignant pain. According to the complaint, to perpetuate an increase in the amount and dosage of opioid prescriptions written for patients, and to optimize the market share for their respective products, the manufacturer defendants also aggressively targeted physicians and other prescribers, essential conduits in the sale of prescription opioids to the public, by having their sales representatives "detail" prescribers in face-to-face meetings, by inviting prescribers to attend informational programs, by hiring "product loyalists" to serve as paid speakers for such programs, and by using data mining to track opioid prescriptions and reward prolific prescribers of their products. Other alleged marketing strategies designed to affect physicians' prescribing practices included advertising in print journals and online, sponsoring continuing medical education courses, and hiring so-called "key opinion leaders" (KOLs) to act as consultants and serve as lecturers.

116. Judge Jerry Garguilo also noted that the plaintiffs alleged that J&J and the other manufacturing defendants funded fake front groups and spread other false information for the purpose of increasing sales of opioids, stating:

> The plaintiffs further allege that the manufacturer defendants' marketing campaigns included funding so-called "front groups," such as the American Pain Foundation and the American Academy of Pain Medicine, which wrote and disseminated favorable educational materials, published "scientific literature" without scientific bases, and created opioid treatment guidelines supporting opioid therapy for chronic pain. According to the complaint, in addition to providing those groups with substantial funding, the manufacturer defendants exercised significant influence over the educational programs and written materials, such as journal articles and treatment guidelines, regarding opioids presented by front groups and KOLs. Moreover, the plaintiffs allege that the manufacturer defendants sponsored websites created by

> front groups and accessible by the public that promoted prescription opioids as a means for improving patients' normal daily functions and quality of life.

117. On these allegations, the New York state court held that the plaintiffs "sufficiently allege[d] materially deceptive acts and practices by the manufacturer defendants that undermined consumers' ability to assess the benefits and dangers of prescription opioids and to make informed decisions as to the efficacy and safety of opioid therapy for chronic pain."

118. In November 2018, the New Jersey Attorney General filed a complaint against the Company in New Jersey state court accusing it of excessively distributing opioids in that state and of pushing opiates with marketing schemes premised on misleading statements about their risks and benefits. According to the complaint, Janssen deceptively marketed NUCYNTA pain relievers as safer and milder than other prescription opioids by claiming that NUCYNTA products were "unlike traditional opioids" and possessed "non-opioid" properties. The complaint alleges that "[t]his doublespeak ... masked the reality that Nucynta and Nucynta ER are not milder and are not less addictive" than other opioids categorized under Schedule II of the Controlled Substances Act.

119. On April 2, 2019, the Honorable Declan P. Mansfield denied the Company's motion to dismiss another lawsuit, filed in Florida state court, accusing J&J and others of misleading doctors into overprescribing opioids. In that lawsuit,

Florida Attorney General Ashley Moody alleged that J&J conspired with other opioid distributors to sell and ship "ever-increasing quantities" of opioids into Florida, while using misleading marketing to convince doctors and their patients that opioids could be safely prescribed for chronic pain. According to the complaint, the companies knew or should have known there was no legitimate scientific basis for their claims to doctors and patients, yet they continued deceptively marketing and selling the drugs.

120. On August 26, 2019, the Honorable Thad Balkman ordered J&J to pay the state of Oklahoma $465 million after finding that J&J had intentionally downplayed the dangers and oversold the benefits of opioids. Judge Balkman found that J&J promulgated "false, misleading, and dangerous marketing campaigns" that "caused exponentially increasing rates of addiction, overdose deaths" and babies born exposed to opioids. On these findings, Judge Balkman ruled that J&J perpetuated a "public nuisance," substantially contributing to an ongoing public health crisis that could take decades to abate. In his order, Judge Balkman detailed J&J's deceptive conduct, stating that "[t]he greater weight of the evidence shows that Defendants did, in fact, engage in such false and misleading marketing" and specifically that:

> Among other things, they sent sales representatives into Oklahoma doctors' offices to deliver misleading messages, they disseminated misleading pamphlets, coupons, and other printed materials for patients and doctors, and they misleadingly advertised their drugs over the

> internet-all of which occurred here in Oklahoma. But Defendants also pervasively promoted the use of opioids generally. This "unbranded" marketing included things like print materials that misleadingly touted the safety and efficacy of opioids as a class of pain medication, as well as online materials that promoted opioids generally. Defendants used and viewed medical education events (including Speakers Bureau sessions and CME opportunities) as promotional endeavors that Defendants leveraged to increase the market for opioids through misleading messaging.
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> * * *
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> ***According to Defendants' own internal training documents,*** Defendants concede that "False and Misleading" promotion includes at least the following types of conduct: ***Broadening of product indication;*** Data taken out of context; Minimization of safety issues; Omission of material information; Comparative efficacy or safety claims without substantial evidence; and Overstatements of efficacy or safety. … The greater weight of the evidence demonstrated that Defendants engaged in promotional activities that violated each one of these rules.

121. On September 4, 2019, the Honorable Dan Aaron Polster denied J&J and Janssen's motion for summary judgment in the MDL, finding that plaintiffs had alleged facts sufficient to support a RICO (Racketeer Influenced and Corrupt Organizations Act) claim against J&J and Janssen for participating in a criminal enterprise to pay kickbacks to doctors and disseminate false and misleading statements to promote opioid prescriptions and sales. Judge Polster found "Plaintiffs presented evidence sufficient to support a finding that each Manufacturer, including Janssen, engaged in misleading marketing activities that resulted in a substantial increase in the supply of prescription opioids and proximately caused harm to Plaintiffs." In doing so, Judge Polster noted that (i) "Plaintiffs point to evidence that

suggests … Janssen contributed substantial sums of money to third parties who published misleading statements about prescription opioid use"; (ii) "Plaintiffs present evidence that, as part of its unbranded marketing efforts, Janssen funded third-party speech. Construing this evidence in the light most favorable to Plaintiffs, a jury could reasonably conclude these third-party statements constituted commercial speech that contained false and misleading statements regarding the risks and benefits of prescription opioid use, and that Janssen supported that speech for its own commercial benefit"; and (iii) "[E]ach Manufacturer, including Janssen, failed to maintain effective controls against diversion [of opioids to the black market]."

122. In mid-October 2019, media outlets reported that the Company had reached an agreement in principle with four attorneys general pursuant to which it would pay approximately ***$4 billion*** to settle the lawsuits in the U.S. accusing J&J of fueling the opioid epidemic.

123. On October 28, 2019, the Company reported that it had received in August a grand jury subpoena from the U.S. Attorney's Office for the Eastern District of New York related to its opioid medication policies. According to J&J's Quarterly Report on Form 10-Q filed with the SEC that day, the investigation relates to monitoring and reporting programs by manufacturers and distributors of opioids under the Controlled Substances Act.

DAMAGES TO J&J

124. The Individual Defendants' participation in the wrongdoing detailed above and failure to remedy the Company's improper business practices has exposed J&J to billions of dollars in liability for individual and class action lawsuits. J&J and Janssen have been named as defendants in thousands of lawsuits brought by various state and local governments related to their deceptive marketing of opioids. As the Company admitted in its Quarterly Report on Form 10-Q filed with the SEC on October 28, 2019, "[a]n adverse judgment in any of these lawsuits could result in the imposition of large monetary penalties and significant damages including, punitive damages, cost of abatement, substantial fines, equitable remedies and other sanctions."

125. Further, the Company has already been hit with hundreds of millions of dollars in judgments on claims that it intentionally downplayed the dangers and oversold the benefits of opioids. On August 26, 2019, the Honorable Thad Balkman ordered J&J to pay the state of Oklahoma $465 million after finding that the Company promulgated false, misleading, and dangerous marketing campaigns that caused exponentially increasing rates of addiction, overdose deaths, and babies born exposed to opioids. Two months later, on October 1, 2019, the Company announced that it had agreed to pay $20.4 million to resolve similar lawsuits in two Ohio counties.

126. The Individual Defendants' unwillingness to halt J&J's deceptive marketing and promotion of opioids also damaged the Company's reputation. In addition to price and product quality, J&J's current and potential customers consider a company's trustworthiness and ability to truthfully market its products. Customers are less likely to do business with companies that knowingly permit and/or encourage unscrupulous behavior. As a September 11, 2019 *Forbes* article titled "J&J Shares Recover Amid $571 Million Fine, But Its Reputation May Never Recover," reported: "The Dow may care little for corporate ethics, but let's not forget that J&J's crown jewels are its line of baby care, first aid products, and household remedies, and unlike Wall Street, mothers don't as easily forgive or forget." An October 14, 2019 PRWeek.com article similarly pointed out the reputational damage the Company has suffered as a result of its involvement in the opioid crisis, stating: "Johnson & Johnson's public reputation is nearly at rock bottom of a new global ranking of the pharma industry." The article quoted Alva, a reputation intelligence company, as stating: "So far, we have seen clear evidence that J&J's reputation has been negatively affected by the issues it is facing. The key risk beyond the lawsuits and settlement costs is clearly the erosion of the company's brand promise."

127. Further, as a direct and proximate result of the Individual Defendants' actions, J&J has expended, and will continue to expend, significant sums of money. Such expenditures include, but are not limited to:

(a) costs incurred in defending and paying any potential settlement or adverse judgment in the thousands of lawsuits stemming from the Company's deceptive marketing and promotion of opioids;

(b) costs incurred from complying with the governmental investigations resulting from the improper practices detailed above; and

(c) costs incurred in connection with compensation and benefits paid to the Individual Defendants who have breached their duties to J&J.

PLAINTIFFS' DERIVATIVE AND DEMAND REFUSAL ALLEGATIONS

128. Plaintiffs bring this action derivatively in the right and for the benefit of J&J to redress injuries suffered, and to be suffered, by the Company as a direct result of breaches of fiduciary duty by the Individual Defendants. J&J is named as a nominal defendant solely in a derivative capacity. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.

129. Plaintiffs will adequately and fairly represent the interests of J&J in enforcing and prosecuting its rights.

130. Plaintiffs were stockholders of J&J at the time of the wrongdoing complained of, have continuously been stockholders since that time, and are current J&J stockholders.

131. Under New Jersey law, where a corporation rejects a stockholder demand to bring suit against the corporation's fiduciaries for misconduct, the

relevant questions are: (i) whether or not a majority of the board of directors was independent at the time of the determination by the board; and (ii) whether the independent directors made the determination in good faith after conducting a reasonable inquiry upon which the conclusions are based. N.J. Stat. §14A:3-6.5. Here, the Demand Board bears the burden of proving that, in deciding to reject Plaintiffs' Demand and/or to seek to terminate this derivative litigation, the members of the Demand Board (1) were independent and disinterested, (2) acted in good faith and with due care in investigating Plaintiffs' allegations, and (3) made a decision (here, to reject Plaintiffs' Demand in its entirety) that was reasonable.

132. In the context of a stockholder demand, directors are duty-bound to inform themselves of all material information reasonably available to them. A board's refusal of a litigation demand is not entitled to the protections of the business judgment presumption where the investigation upon which it is based is so restricted in scope as to constitute a pretext. A stockholder demand is also wrongfully refused when it is evident that the directors prejudged the merits of the suit and then conducted the investigation with the object of putting together a report that demonstrated the suit has no merit. Further, a demand refusal is wrongful where there is reason to doubt that the board acted independently and disinterestedly in investigating the allegations and in responding to the demand.

133. Here, the Demand Board failed to act independently and in good faith with respect to Plaintiffs' Demand, and then based its decision to refuse the Demand on an inadequate and unreasonable investigation that failed to gather, present and fairly evaluate all reasonably available material information, as required by the business judgment rule. Accordingly, the Board's refusal of the Demand was wrongful, and Plaintiffs have standing to pursue the claims on behalf of J&J and its stockholders.

Relevant Background

A. Plaintiffs Send the Board a Detailed Litigation Demand

134. Plaintiffs sent the Demand to the Board on April 18, 2019. The Demand was substantive and detailed. Having presented the Board with substantially similar facts to those alleged in this Complaint, Plaintiffs demanded that the Board (1) commence an independent investigation into the matters raised in Plaintiffs' Demand; (2) take any and all appropriate steps for the Company to recover, through litigation if necessary, the damages proximately caused by the directors' and officers' breaches of fiduciary duty; and (3) implement corporate governance enhancements to prevent a recurrence of the alleged wrongdoing.

135. Plaintiffs demanded that the Board gather facts relevant to and thoroughly analyze and evaluate the following matters, at a minimum:

1. The roles of current and former J&J directors and officers in the monitoring and enforcing compliance with health standards and ensuring the safety of the Company's products;

2. Actions taken by J&J directors and officers responsible for disseminating misleading information concerning J&J's opioid products and opioids in general;

3. Actions taken by J&J directors and officers responsible for and/or had knowledge of the Company's deceptive opioid marketing and promotional practices;

4. Actions taken by J&J directors and officers responsible for and/or had knowledge of the Company's inadequate disclosure controls; and

5. Actions taken by J&J directors and officers responsible for making, reviewing, approving, and/or in any way overseeing the issuance of improper statements.

136. Plaintiffs also demanded that, following the investigation, J&J commence legal proceedings against each party identified as being responsible for the mismanagement and breaches of fiduciary duty described in the Demand. Further, Plaintiffs demanded that the Board take all necessary actions to reform and improve J&J's corporate governance and internal procedures to comply with all applicable laws and to protect the Company from harm arising from similar wrongdoing in the future.

137. Finally, given the expiration of the statute of limitations, the Demand sought evidence of existing and/or new agreements tolling the statute of limitations as to any individual who could potentially face liability in connection with any claims that might be in the Company's interest to pursue.

B. The Board Initially Blows Off Plaintiffs' Demand

138. Plaintiffs received a response letter from Sidley Austin on behalf of the Company on May 3, 2019.[21] The Company's brief letter stated that Lowenstein was investigating the "underlying matters regarding the Company's opioid products that are addressed in [the Demand]." Although the Company's letter disclosed that Douglas Eakeley from Lowenstein was leading the investigation, it did not state who at J&J Mr. Eakeley was reporting to, nor whether the Board had established a committee to oversee the investigation. With respect to details of the investigation, the letter merely provided that the investigation was "underway and [wa]s currently in the fact-gathering stage." Notably, the Company's letter did not delineate the scope of the investigation, nor the anticipated duration of the investigation. Neither did the Company's letter address whether the Board had secured tolling agreements from potential defendants, as Plaintiffs had expressly demanded in the Demand.

139. Over six months later, after receiving scant information regarding the scope and timing of the investigation, on October 21, 2019, Plaintiffs' counsel wrote to J&J's counsel inquiring into the status of the investigation into the Demand.[22] Plaintiffs noted that J&J had recently agreed to pay $20.4 million to resolve claims

[21] A true and correct copy of the May 3, 2019 letter is attached hereto as Exhibit B.

[22] A true and correct copy of the October 21, 2019 letter is attached hereto as Exhibit C.

brought by two Ohio counties alleging that J&J fueled the opioid crisis in the U.S. Plaintiffs also identified reports indicating that J&J was proposing to pay $4 billion to resolve portions of the opioid MDL. Plaintiffs stressed the importance of having independent individuals overseeing the Company's entrance into these agreements, and urged J&J to act expeditiously to hold those responsible for damaging the Company accountable. Plaintiffs also requested the names of the Board members charged with overseeing the Company's opioid litigation efforts.

140. Sidley Austin responded with a one-page letter on November 1, 2019.[23] In the letter, counsel did little more than reiterate that Mr. Eakeley of Lowenstein was leading the investigation into J&J's opioid marketing practices. Counsel did not address Plaintiffs' request for the names of the Board members charged with overseeing the Company's opioid litigation efforts. Nor did counsel mention Plaintiffs' previous demand that J&J enter into tolling agreements with all potential defendants.

141. On November 11, 2019, Plaintiffs' counsel sent Sidley Austin another letter.[24] In the letter, Plaintiffs' counsel expressed concern over the Board's delay in

[23] A true and correct copy of the November 1, 2019 letter is attached hereto as Exhibit D.

[24] A true and correct copy of the November 11, 2019 letter is attached hereto as Exhibit E.

investigating Plaintiffs' Demand and requested written confirmation that the Company had entered into tolling agreements with the potentially culpable fiduciaries. Plaintiffs' counsel also sought confirmation that the Company had not released any claims covered by the Demand. Finally, Plaintiffs' counsel noted that under New Jersey law, they were entitled to take action given the Board's delay in responding.

142. In a brief letter dated December 6, 2019, Sidley Austin responded, reiterating that it remained uncertain when the investigation would be complete.[25] Further, despite Plaintiffs having first demanded that the Company secure tolling agreements against the culpable fiduciaries nearly eight months prior, defense counsel stated that J&J was only now considering the request. Counsel did not address Plaintiffs' request for confirmation that the Company had not released any claims covered by the Demand.

143. Nearly seven months after Plaintiffs sent their Demand—nearly three times the statutory period—and without a substantive response from J&J's Board at

[25] A true and correct copy of the December 6, 2019 letter is attached hereto as Exhibit F.

that time despite their obligation under section 14A:3-6.3 to respond to the Demand within ninety days,[26] Plaintiffs commenced this derivative litigation.

C. The Demand Board Formally Refuses Plaintiffs' Demand

144. On April 13, 2020, Douglas S. Eakeley of Lowenstein delivered to J&J's Board the findings of Lowenstein's investigation in the form of the 2020 Report, which ultimately concluded that there was no breach of duty by J&J's Board or senior management.[27] As discussed *infra*, the 2020 Report was based on an unreasonable and deeply flawed investigation.

145. Despite the serious issues with the 2020 Report, the Board did not conduct a meaningful review of Lowenstein's findings and ultimate conclusion that the Company should not pursue any claims. The Demand Board[28] held just a single meeting, on April 23, 2020, to discuss the 2020 Report's recommendations. Without any follow-up, the Demand Board simply adopted Lowenstein's recommendation and resolved to "refuse[] the demands investigated by Mr. Eakeley as contrary to the best interests of the Company, decline[] to have the Company pursue the litigation contemplated in the shareholder demands, and direct[] that the Company take such

[26] Under the statutory requirements, the required ninety-day period expired on July 17, 2019.

[27] The 2020 Report is attached hereto as Exhibit H.

[28] The full Board, with the exception of defendant Gorsky, attended the meeting.

steps as are necessary and appropriate to secure dismissal of the related derivative litigation[.]"

146. On April 28, 2020, Sidley Austin, outside counsel for J&J, provided a terse, one-page letter to Plaintiffs' counsel, rejecting Plaintiffs' Demand in its entirety (the "Refusal Letter").[29]

The Board Failed to Conduct an Independent, Good Faith, and Reasonable Investigation of Plaintiffs' Demand

A. The Board Lacked Sufficient Independence to Impartially Consider Plaintiffs' Demand

147. Under New Jersey law,[30] the Board was required to conduct an independence assessment prior to engaging in its investigation and ultimately seeking to terminate this derivative litigation. Yet, the Board failed to conduct any such independence evaluation. The Board also never asked the Court to appoint "a panel of one or more individuals to make a determination whether the maintenance of the derivative proceeding is in the best interests of the corporation," as provided for in N.J. Stat. §14A:3-6.5(6). And the Board never assigned duties to and failed to form "a committee consisting of one or more independent directors appointed by majority vote of independent directors, or one independent director if the board consists of only one independent director," as N.J. Stat. §14A:3-6.5(2)(b) permits.

[29] The Refusal Letter is attached hereto as Exhibit I.

[30] N.J. Stat. §14A:3-6.5.

Despite the Board members all being implicated in the alleged wrongdoing, the full Board, with the exception of defendant Gorsky, maintained the sole discretion to decide the outcome of Plaintiffs' Demand.

148. This is not a case of a stockholder alleging a lack of independence or disinterestedness simply because the directors are named in a stockholder's litigation demand. On the contrary, the evidence of wrongdoing by the members of J&J's Board in this case is plentiful.

149. Plaintiffs' Demand explained that the Company's fiduciaries, including members of the Demand Board (defendants Mulcahy, Prince, Perez, I. Davis, Williams, Washington, McClellan, S. Davis, and Beckerle), subjected the Company to numerous lawsuits and governmental investigations as a result of their failure to address deceptive practices in marketing and promotion of opioids through Janssen. In particular, the Demand pointed to "more than 1,600 lawsuits brought by various state and local governments related to the marketing of opioids." Exhibit A at 27. The Demand highlighted that "[t]he Company and JPI have also received subpoenas or requests for information related to its opioid marketing practices from at least eight state Attorneys General." *Id*. Further, the Demand noted that "[i]n September 2017, the Company and JPI received requests for documents and information on behalf of Attorneys General from a coalition of states who are investigating the distribution of prescription opioid pain medication." *Id*.

150. Additionally, as outlined in the Demand, the Company "received requests for information from the ranking minority member of the United States Senate Committee on Homeland Security and Governmental Affairs regarding the sales, marketing, and educational strategies related to the promotion of opioid use." *Id*.

151. The Demand also discussed the fact that "in November 2018, the New Jersey Attorney General filed a complaint against the Company in New Jersey state court accusing J&J of excessively distributing opioids in that state and of pushing opiates with marketing schemes premised on misleading statements about their risks and benefits." *Id*. That complaint alleged that J&J "deceptively marketed Nucynta pain relievers as safer and milder than other prescription opioids by claiming that the Nucynta products were 'unlike traditional opioids' and possessed 'non-opioid' properties." *Id*.

152. In another lawsuit in Florida state court "accusing J&J and others of misleading doctors into overprescribing opioids," the court "denied the Company's motion to dismiss" in April 2019. *Id*. The lawsuit "alleged that J&J conspired with other opioid distributors to sell and ship 'ever-increasing quantities' of opioids into Florida, while using misleading marketing to convince doctors and their patients that opioids could be safely prescribed for chronic pain." *Id*. The complaint further alleged "the companies knew or should have known there was no legitimate

scientific basis for their claims to doctors and patients, yet they continued deceptively marketing and selling the drugs." *Id*.

153. In a follow-up to the Demand, dated October 21, 2019, Plaintiffs expressed concern that "in recent weeks J&J agreed to pay $20.4 million to resolve claims by two Ohio counties that the Company fueled the U.S. opioid crisis." Exhibit C at 1. Separately, the follow-up letter alerted the Demand Board to the Company's proposal "to pay at least $4 billion to resolve other portions of the opioid multidistrict litigation." *Id*.

154. The Board's determination to not pursue claims in the face of the liability discussed in the Demand (and herein) was utterly unsurprising given the Board's lack of disinterestedness and independence and corresponding inability to impartially and objectively consider what was in the best interests of J&J. Any finding other than refusing the Demand would have required the Demand Board to admit liability for wrongdoing in various actions across the country – wrongdoing that has caused enormous harm to J&J. When directors prejudge the merits of a suit based on their personal legal exposure, and then conduct the investigation with the object of putting together a report that demonstrates the suit has no merit, it results in a wrongful refusal. Such is the case here.

B. The Selection of Lowenstein to Spearhead the Investigation Reflects the Board's Lack of Independence and Predetermination to Reject Plaintiffs' Demand

155. The Board's decisions to hire Lowenstein and then to authorize Lowenstein to expand the scope of its investigation to cover the wrongdoing in Plaintiffs' Demand further reflect the Board's lack of independence and prejudice with respect to Plaintiffs' allegations.

156. In October 2017, the Board retained Lowenstein to investigate allegations asserted by another stockholder demand relating to J&J's sale of opioids. The Board subsequently authorized Lowenstein to expand the scope of the investigation to include the allegations asserted in Plaintiffs' Demand, including allegations that current and former J&J directors and officers breached their fiduciary duties in connection with J&J's unlawful promotion and sale of opioid medications.

157. This was not the first time the Board had retained Lowenstein to investigate stockholder demands and derivative litigation asserting breaches of fiduciary duty. Nor was it the first time that the Board had determined not to pursue potentially viable derivative claims on the heels of a corporate investigation spearheaded by Douglas Eakeley and his firm, Lowenstein. On the contrary, Lowenstein appears to be a "go-to" law firm for J&J's Board when faced with serious allegations of misconduct. Indeed, the firm has an established track record of

performing perfunctory corporate investigations designed from the outset to exonerate J&J's fiduciaries from all manner of corporate wrongdoing. J&J's Board was well aware of this track record at the time it retained Lowenstein in 2017 and subsequently authorized Lowenstein to expand the scope of its investigation to cover the wrongdoing set forth in Plaintiffs' Demand.

158. In the spring of 2010, a special committee of the J&J Board retained Lowenstein to investigate allegations raised in a number of stockholder demands and derivative complaints. In particular, Lowenstein was retained to assist the special committee's investigation of an array of alleged wrongdoing, including allegations that J&J: (i) paid illegal kickbacks to induce the purchase and recommendation of J&J's medications; (ii) engaged in improper off label marketing of drugs and other products; (iii) had insufficient internal controls at its pharmaceutical manufacturing plants that led to product recalls and caused the Company to enter into a consent decree with the U.S. Department of Justice (the "DOJ"); (iv) knowingly concealed design defects in its branded hip replacements; (v) improperly paid surgeons to use hip and knee replacement products manufactured by a J&J subsidiary; and (vi) bribed Iraqi government officials in violation of the Foreign Corrupt Practices Act.

159. In connection with its prior investigation, Lowenstein prepared a largely boilerplate report detailing its "findings" and the recommendations of the

special committee with respect to the viability of derivative claims asserted in the prior demands and complaints (the "2011 Report").[31] The 2011 Report details that, after "an extensive investigation," the special committee, "[w]ith the assistance of Lowenstein," determined that the myriad forms of wrongdoing outlined in the prior demands "d[id] not warrant litigation by or on behalf of the Company." The 2011 Report further recommended that "the Board of Directors … take whatever steps are necessary or appropriate to reject the various shareholder demands and seek dismissal of the derivative actions." The Board subsequently adopted the findings and recommendations detailed in the 2011 Report and moved to dispose of the derivative claims.

160. As set forth above and in Plaintiffs' Demand, J&J has already been found liable for at least $485 million in damages stemming from the Company's improper opioid sales and marketing activities. In addition, the Company remains the target of thousands of other state and federal lawsuits that seek billions of dollars more in damages as a result of J&J's promotion and sale of opioids. Given the perfunctory nature of Lowenstein's prior investigation, it is unfortunate, but not entirely surprising, that the Board again turned to Lowenstein to investigate their

[31] The 2011 Report is attached hereto as Exhibit G.

actions (and inaction) relating to the Company's decision to engage in business practices that fueled the opioid epidemic.

1. The Failure to Assess Lowenstein's Objectivity Demonstrates the Board's Interest in Quickly Disposing of Plaintiffs' Demand

161. The record indicates that the Board never considered whether Lowenstein's prior investigation had the potential to create debilitating conflicts of interest before the Board decided to reengage Lowenstein in 2017—and subsequently authorized the firm to expand its investigation to encompass Plaintiffs' Demand. This was a significant failure. In connection with its prior investigation, Lowenstein made certain representations and recommendations concerning J&J that were reasonably likely to affect Lowenstein's ability to objectively assess the wrongdoing identified by Plaintiffs in this case and the viability of potential derivative claims.

162. In connection with its investigation of Plaintiffs' Demand, Lowenstein was asked to address the adequacy of J&J's internal controls, including those relating to compliance with the various rules and regulations governing the sale and marketing of opioid medications. However, during its prior engagement, Lowenstein, along with the special committee, made certain affirmative representations about the adequacy of J&J's internal controls. For instance, the 2011 Report states that the earlier investigation found that J&J's "systems are designed to

assure full compliance with all applicable laws and regulations, and include regular reporting and monitoring by the J&J Board of Directors and its Audit Committee." The 2011 Report further represents that "at the J&J Corporate level, the sales and marketing compliance systems at the subsidiary level have grown and strengthened over time," and that the 2011 investigation "found no evidence to suggest that the Board became aware of illegal marketing activity and failed to take steps to prevent it."

163. Because Lowenstein, along with the special committee, determined that J&J's internal controls were adequate, they made just a single recommendation to the Board in connection with the 2011 investigation: that J&J create a new board-level committee—the Regulatory and Compliance Committee—to oversee J&J's compliance systems and organization. This lone corporate governance reform was subsequently adopted by the Board.

164. It appears that the Board never considered Lowenstein's prior affirmative representations about J&J's internal controls, including whether those representations could hinder the firm's ability to objectively assess the wrongdoing detailed in Plaintiffs' Demand. For instance, it does not appear that the Board considered that Lowenstein might be predisposed to finding that J&J's controls relating to the sale and marketing of opioids were adequate in light of Lowenstein's previous representations regarding the Company's internal controls over regulatory

compliance—including those relating to compliance with rules governing the sale and marketing of prescription medications.

165. In addition, the record does not suggest that the Board ever considered the likelihood that Lowenstein would be reluctant or even unwilling to identify control deficiencies or propose additional governance reforms for fear of reprisal. Indeed, it is not difficult to imagine that the Board would blame Lowenstein if its investigation of Plaintiffs' Demand uncovered control deficiencies or corporate wrongdoing that went undiscovered during its prior investigation. For the same reason, it is also clear that Lowenstein may have been hesitant to recommend any sweeping governance reforms, given its prior representations about the adequacy of J&J's controls and the limited nature of the corporate governance reforms the firm previously proposed in connection with the 2011 investigation.

166. The Board's failure to consider these potential conflicts of interest before reengaging Lowenstein, along with its failure to establish any safeguards to prevent these conflicts from materializing after Lowenstein was retained, underscore that the investigation was not conducted in good faith. Similarly, the failure of Lowenstein to disclose its potential conflicts in the 2020 Report, or to take any steps to affirmatively address or mitigate these potential conflicts, demonstrates the lack of independence with which the firm approached its investigation of Plaintiffs' Demand.

2. The Contents of the 2020 Report Demonstrate that Lowenstein Lacked Independence and Failed to Conduct a Reasonable Investigation

167. The 2020 Report picks up right where Lowenstein left off in 2011. The 2020 Report, like the earlier 2011 Report, reaches the same predetermined conclusions that the Board undoubtedly sought when it again decided to retain Lowenstein: that the Company should take no action whatsoever to hold members of the Board or senior management accountable for the tremendous damage caused by J&J's improper opioid sales and marketing activities.

168. ***Identical Conclusions***: The conclusions rendered in the 2020 Report and 2011 Report are nearly identical. As detailed below, Lowenstein merely updated the conclusions in the 2020 Report to reflect the fact that here (unlike during the prior investigation), the Board failed to appoint a special committee to investigate Plaintiffs' Demand:

2020 Report	2011 Report
We therefore recommend that the Board should reject the Shareholder Demand Letters and take whatever steps necessary or appropriate to secure dismissal of the Derivative Complaints.	The Special Committee therefore recommends to the Board of Directors that the Company take whatever steps are necessary or appropriate to reject the various shareholder demands and seek dismissal of the derivative actions.
As the preceding sections of this Report make clear, we believe that it is not in the best interests of the Company to initiate litigation based upon the claims in the Shareholder Demand Letters or to	Given the foregoing, the Special Committee believes that it is not in the best interests of the Company to pursue the derivative litigation currently pending or to initiate litigation based

pursue the currently pending derivative litigation.	upon the demands made upon the Board by the demand shareholders.
We therefore recommend that the Board should reject the Shareholder Demand Letters and take whatever steps are necessary or appropriate to secure dismissal of the Derivative Complaints.	The Special Committee therefore recommends to the Board of Directors that the Company reject the shareholder demands and take whatever steps are necessary or appropriate to secure dismissal of the derivative litigation.

169. The similarities between Lowenstein's 2020 Report and 2011 Report go beyond just reaching the same topline conclusions. Rather, it appears that in drafting the 2020 Report, Lowenstein copied and pasted entire sections from its prior report. Further, it appears that Lowenstein merely updated, or otherwise revised, other sections of the 2020 Report to reflect allegations specific to the opioid wrongdoing instead of the earlier wrongdoing. And, like the 2011 Report, the 2020 Report is also divided into the exact same five sections.[32]

170. ***Identical Rationale for Refusal***: Critically, the portions of the 2020 Report that Lowenstein directly copied (or repurposed with slight modifications) from its earlier report are not mere boilerplate. For instance, as set forth below, the portion of the 2020 Report outlining the rationale behind Lowenstein's

[32] The 2020 Report and 2011 Report are divided into the same five sub-parts. In both reports, part one consists of an introduction; part two summarizes the alleged wrongdoing and scope of the investigation; part three outlines the applicable legal standards; part four consists of the factual findings; and part five outlines the conclusions and recommendations.

recommendations that the Board should not pursue litigation and should reject Plaintiffs' Demand appears to be copied, nearly verbatim, from the 2011 Report:

2020 Report	2011 Report
J&J continues to be subject to lawsuits and government investigations in connection with the matters raised in the Shareholder Demand Letters and Derivative Complaints. If the Company initiates or adopts derivative litigation, statements made by the Company or its representatives in pleadings, depositions or at trial could be deemed admissions and used against the Company in collateral litigation. In addition, to the extent that J&J takes positions in litigation against present or former officials and prevails, the result could be used against J&J in collateral litigation.	As described in more detail below, J&J continues to be subject to lawsuits and government investigations in connection with some of the same matters raised by the shareholder allegations. Thus, if the Company adopts derivative litigation, statements made by the Company or its representatives in pleadings, depositions, or at trial could be deemed admissions and used against the Company in collateral litigation. In addition, to the extent that J&J takes positions in litigation against present or former officials and prevails, the result could be used against J&J and the Company could be prevented from taking an inconsistent position in collateral litigation.
The indemnified director or officer is entitled to indemnification against expenses (including legal fees), judgments, fines, penalties, and settlements paid or reasonably incurred. Thus, if derivative litigation is pursued by the Company against certain officers and directors, J&J may be required to advance all reasonable expenses incurred by each of the named defendants in defending the action. The expenses and amounts paid in a settlement may also be subject to	The indemnified director or officer is entitled to indemnification against expenses (including legal fees), judgments, fines, penalties and settlements paid or reasonably incurred. Thus, if derivative litigation is pursued by the Company against certain officers and directors, J&J may be required to advance each of the named defendants all reasonable expenses incurred in defending the action. The expenses and amounts paid in a settlement may also be subject to

2020 Report	2011 Report
indemnification, depending on the nature of the conduct at issue.	indemnification, depending on the nature of the conduct at issue.
The Company's Directors and Officers insurance policy contains a standard "insured against insured" exclusion, pursuant to which, were the Company to bring suit against its directors and officers, damages awarded to the Company as a consequence of wrongful acts of an insured officer or director may not be recovered under the policy, leaving only the personal assets of the officer or director as a source of compensation. However, the policy also contains an exception to the exclusion in the case of a derivative complaint brought by shareholders who are not insured under the policy.	The Special Committee also considered the application of insurance and whether J&J's insurance policy would apply if the Board adopted the derivative litigation and brought the claims itself. The Company's policy contains a standard "insured against insured" exclusion, pursuant to which damages incurred by the Company as a consequence of wrongful acts of an insured officer or director may not be recovered under the policy, leaving only the personal assets of the officer or director as a source of compensation. However, the policy also contains an exception to the exclusion, in the case of a derivative complaint brought by shareholders who are not insured under the policy.
Any litigation pursued by or on behalf of J&J would involve a substantial commitment of time and resources. Although many of the allegations in the Shareholder Demand Letters and Derivative Complaints appear to be duplicative of claims asserted in other litigation against the Company and/or its subsidiaries, J&J would nonetheless have to devote substantial resources to the claims discussed in the Shareholder Demand Letters and the Derivative Complaints.	Any litigation pursued by or on behalf of J&J would involve a substantial commitment of time and resources. Although many of the claims asserted derivatively appear to be duplicative of claims asserted in other litigation against the Company and/or its subsidiaries, J&J would nonetheless have to devote substantial resources to prosecuting the derivative claims.

2020 Report	2011 Report
The Board should also consider the potential detrimental effect that litigation could have on J&J's business and operations. Litigation against current or former directors or officers might also damage employee morale and the Company's relationship with its employees.	The Special Committee also considered the potential detrimental effect that litigation could have on J&J's business and operations. Litigation against current or former directors or officers might damage employee morale and the Company's relationship with its employees. In addition, a derivative litigation could cause distractions and negatively impact the Company's focus on remedial measures, including compliance with the March 11, 2011 McNeil Consent Decree, discussed below.

171. ***Identical Examination of Internal Controls***: The 2020 Report also appears to have directly copied (or repurposed with slight modifications) sections of the 2011 Report that addressed J&J's internal controls, the duties of senior management and members of the Board, as well as the legal standards applicable to their review of Plaintiffs' Demand. The 2020 Report even characterizes the allegations in Plaintiffs' Demand in a similar fashion to how the 2011 Report characterized the earlier demands and derivative suits. A few of the similarities described in this paragraph are summarized and reflected below:

2020 Report	2011 Report
The gravamen of the Shareholder Demand Letters and the Derivative Complaints is that the named J&J officers and directors breached their fiduciary duties by permitting the allegedly wrongful conduct and by ignoring "red flags" that such conduct was occurring.	The gravamen of the demand letters and derivative complaints is that the named J&J officers and directors breached their fiduciary duties owed to the Company by permitting a variety of improper activities to occur across various business segments, and by ignoring "red flags" that such conduct was occurring.
J&J has several important corporate governance documents. First, J&J is a credo-based company; Robert Wood Johnson, the former Chairman from 1932 to 1963 and a member of the Company's founding family, crafted the J&J "Credo" in 1943. The Credo challenges J&J to put first the needs and well-being of the patients, doctors, and nurses it serves. It also sets forth the Company's responsibilities to its employees, the local and global communities, and its shareholders.	J&J has several important corporate governance documents. First, J&J is a credo-based company. Robert Wood Johnson, the former Chairman from 1932 to 1963 and a member of the Company's founding family, crafted the J&J "Credo" in 1943. The Credo challenges J&J to put first the needs and well-being of the doctors, nurses, patients, and customers that it serves. It also sets forth the Company's responsibilities to its employees, the local and global community, and its shareholders.
[T]he Code of Business Conduct & Ethics for the members of the Board and Executive Officers of the Company sets forth the requirements for directors and officers with respect to conflicts of interest, fair dealing, gifts, compliance with laws and regulations, use of non-public information and disclosure, and use of Company funds.	[T]he Code of Business Conduct and Ethics for Members of the Board of Directors and Executive Officers sets forth the requirements for directors and officers with respect to conflicts of interest, fair dealing, gifts, compliance with laws and regulations, use of non-public information and disclosure, and use of Company funds.
With more than 260 operating companies located throughout the world, J&J views its governance model	With more than 250 operating companies located throughout the world, J&J views its decentralized

2020 Report	2011 Report
as an asset and fundamental to the success of its broadly based health care business. This model allows each of its individual operating companies to function in a smaller company setting, while drawing upon the resources of a Fortune 50 company.	model as an asset and fundamental to the success of its broadly-based health care business. This model allows each of its individual operating companies to function in a small company setting, while drawing upon the resources of a Fortune 50 company.
Each business segment is led by a Worldwide Chair, who also heads the respective sector's Group Operating Committee ("GOC"). The GOCs, which are comprised of senior managers, oversee and coordinate the activities of the domestic and international operating companies within the sectors. Each operating company is led by a company Chair, President, General Manager or Managing Director, who, in turn, reports directly, or through a line executive, to the sector Worldwide Chair and GOC leader.	Each business sector is led by a Worldwide Chairman, who also heads the respective sector's Group Operating Committee ("GOC"). The GOCs, which are comprised of senior managers, oversee and coordinate the activities of the domestic and international operating companies within the sectors. Each operating company is led by a company Chairman, President, General Manager or Managing Director, who, in turn, reports directly, or through a line executive, to the sector Worldwide Chairman and GOC leader.
J&J's Executive Committee is the principal management group responsible for the overall operations and allocation of the resources of the Company. The Executive Committee oversees and coordinates the activities of the Company's three business segments. Ultimately, it reviews financial results and develops strategies and initiatives for long-term growth.	J&J's Executive Committee is the principal management group responsible for the overall operations and allocation of the resources of the Company. The Executive Committee oversees and coordinates the activities of the Company's three business sectors. Ultimately, it reviews financial results and develops strategies and initiatives for long-term growth.
J&J strengthened its corporate oversight of compliance in the late 1990s to early 2000s. At that time, the	J&J strengthened its corporate oversight of Compliance in the late-1990s to early-2000s. At that time, the

2020 Report	2011 Report
Technical Resources Group, along with J&J's Law and Corporate Internal Audit Departments, oversaw compliance at the corporate level. In 1999, the Law Department issued guidance documents called Brightlines, which provided guidance on allowable marketing, promotional, and sales practices under the domestic health care regulatory and fraud and abuse laws. Brightlines were revised periodically to incorporate new guidance documents and updates. To oversee and reduce compliance risks, J&J also began to use and/or improve upon various assessment tools and processes. For instance, J&J introduced the Management Awareness and Review Systems ("MAARS") in 2000. MAARS received input from four primary sources: (1) self-assessments completed by the operating companies; (2) business analyses; (3) joint assessments/internal audits; and (4) testing and monitoring. These inputs were then translated into a management action plan ("MAP") to address Compliance risks or violations. The MAP promoted accountability at the operating company level by setting priorities and identifying resource plans with specific measurable actions and completion dates.	Technical Resources Group, along with J&J's Law and Corporate Internal Audit Departments, oversaw Compliance at the corporate level. In 1999, the Law Department issued guidance documents called "Brightlines," which provided guidance on allowable marketing, promotional, and sales practices under the domestic health care regulatory and fraud and abuse laws. "Brightlines" have been revised periodically to incorporate new guidance documents and updates. To oversee and reduce compliance risks, J&J also began to use and/or improve upon various assessment tools and processes. For instance, J&J has utilized the Management Awareness and Review Systems ("MAARS") since at least 2000. MAARS receive input from four primary sources: (1) self-assessments completed by the operating companies; (2) business analyses; (3) joint assessments/internal audits; and (4) testing and monitoring. These inputs are then translated into a management action plan ("MAP") to address Compliance risks or violations. The MAP promotes accountability at the operating company level by setting priorities and identifying resource plans with specific measurable actions and completion dates.
Several significant corporate organizational changes followed in 2004. The Technical Resources Group was renamed Technical Resources and	Several significant corporate organizational changes followed in 2004. Technical Resources Group was renamed Technical Resources and

2020 Report	2011 Report
Compliance ("TRC"), and the head of TRC was appointed Corporate Compliance Officer, reporting directly to Russell Deyo, J&J's then- Chief Compliance Officer and General Counsel. Moreover, in March 2004, J&J established the Worldwide Office of Health Care Compliance (the "Worldwide HCC"), which was intended to increase corporate oversight of HCC. That same year, J&J restructured the corporate quality governance organization to reflect the global nature of J&J's business as well. The previous corporate quality organization, Quality & Compliance Services, was renamed Quality & Compliance Worldwide ("Q&C Worldwide"). In addition, J&J replaced its Regional Quality Councils with the Global Quality Council ("GQC") and Global Quality Operating Groups aligned with the three business sectors.	Compliance ("TRC"), and the head of TRC, Brenda Davis, was appointed Corporate Compliance Officer, reporting directly to Russell Deyo, J&J's Chief Compliance Officer and General Counsel. Moreover, in March 2004, J&J established the Worldwide Office of Health Care Compliance (the "Worldwide HCC"), which was intended to increase corporate oversight of HCC. That same year, J&J restructured the corporate quality governance organization to reflect the global nature of J&J's business as well. The previous corporate quality organization, Quality & Compliance Services, was renamed Quality & Compliance Worldwide ("Q&C Worldwide"). In addition, J&J replaced its Regional Quality Councils with the Global Quality Council ("GQC") and Global Quality Operating Groups aligned with the three business sectors.
After ramping up its corporate oversight of compliance in the preceding years, in early 2007, J&J restructured the Corporate Center, which provided certain administrative functions such as compliance, information technology, finance, legal and human resources, pursuant to a Corporate Center Review ("CCR") conducted in 2006. The purpose of the CCR, among others, was to clarify the roles of the Corporate Center and operating companies with respect to Compliance, reduce unnecessary	After ramping up its corporate oversight of Compliance in the preceding years, J&J restructured the Corporate Center in early 2007, pursuant to a Corporate Center Review ("CCR") conducted in 2006 with the assistance of the consulting firm McKinsey & Co., Inc. The purpose of the CCR, among others, was to clarify the respective roles of the Corporate Center and operating companies with respect to Compliance, reduce unnecessary burdens on the operating companies, eliminate redundancies and

2020 Report	2011 Report
burdens on the operating companies, eliminate redundancies and inefficiencies, and enhance compliance and operational efficiency. As a result of the CCR, J&J reorganized the Corporate Center and streamlined its role both structurally and functionally. The objective of the restructuring was to "shift accountability for compliance risks to GOC/Franchises" while reducing the burden on the operating companies and sustaining "enterprise-wide Quality & Compliance performance levels."	inefficiencies, and enhance Compliance and operational efficiency. As a result of the CCR, J&J reorganized the Corporate Center and streamlined its role both structurally and functionally. The objective of the restructuring was to "shift accountability for compliance risks to GOC/Franchises," while reducing the burden on the operating companies and sustaining "enterprise-wide Quality & Compliance performance levels."
Shortly after the CCR, J&J appointed a new Chief Compliance Officer in 2007. J&J also created a new Compliance Committee, chaired by the Chief Compliance Officer and comprised of senior leaders from several corporate functions (i.e., Corporate Internal Audit; Human Resources; the Law Department; Worldwide Operations; Q&C Worldwide; Worldwide HCC; Environment, Health and Safety; and Privacy, Information Technology Security) and the three sector Chief Compliance Officers. The Compliance Committee assesses global compliance risk and is responsible for approving sector-specific and corporate policies, procedures and programs, and reports to the Executive Committee and the Audit Committee and Regulatory Compliance Committee of the Board of Directors. The Compliance Committee also oversees HCC, Q&C,	Shortly after the CCR, J&J appointed a new Chief Compliance Officer in 2007. J&J also created a new Compliance Committee, which was chaired by the Chief Compliance Officer and comprised of senior leaders from several corporate functions (i.e., Corporate Internal Audit; Human Resources; the Law Department; Worldwide Operations; Q&C Worldwide; Worldwide HCC; Environment, Health and Safety; and Privacy) and the three sector Chief Compliance Officers. The Compliance Committee is responsible for approving sector-specific and corporate policies, procedures and programs, and reports to the Executive Committee and the Audit Committee of the Board of Directors. The Compliance Committee also oversees HCC, Q&C, environment, health and safety, privacy, anti-corruption laws and

2020 Report	2011 Report
environment, health and safety, privacy, anti-corruption laws and regulations, and compliance with the regulatory requirements of health authorities.	regulations, and compliance with the regulatory requirements of health authorities.
Along with the Compliance Committee, J&J also formed the Triage Committee in 2007, which is chaired by the Chief Compliance Officer and includes the members of the Compliance Committee who represent Corporate Internal Audit, Security, the Law Department, and Human Resources. It was established to assure that serious legal, regulatory or compliance issues were reported to and addressed by senior management in a timely fashion. A "serious issue" includes violations of law by management or multiple employees or that might involve a loss greater than $500,000. The Triage Committee has two standing weekly meetings, during which decisions are made as to which issues should be investigated and by which office.	In addition, J&J formed the Triage Committee in 2007. The Triage Committee consists of the J&J Chief Compliance Officer, as well as the members of the Compliance Committee who represent Corporate Internal Audit, Security, the Law Department, and Human Resources. It was established to assure that serious issues were reported to and addressed by senior management in a timely fashion. A "serious issue" includes violations of law by management or multiple employees or that might involve a loss greater than $500,000. In 2009, J&J also began to characterize all potential violations of FCPA or local anti-corruption laws as serious sensitive issues. The Triage Committee has two standing weekly meetings, during which decisions are made as to which issues should be investigated and by which office.
The Board must decide whether to accept or reject, in whole or in part, the Shareholder Demand Letters demanding that the Board commence a civil action against certain officers and directors for breach of the fiduciary duties of care and loyalty. Relatedly, and with respect to the Derivative	As explained above, the Special Committee must decide whether to accept or reject, in whole or in part, the shareholder letters demanding that the J&J Board of Directors sue certain officers and directors for breach of fiduciary duty, and whether to take other remedial action. The Special

2020 Report	2011 Report
Complaints, the Board must decide whether to seek dismissal of the litigation, intervene in and take over such litigation, or allow the litigation to proceed on behalf of J&J without intervention. The pertinent legal standards and factors for such an analysis are set forth below.	Committee must also decide whether to intervene in and take over the derivative litigation, seek its dismissal, or stay on the sidelines and let the plaintiffs proceed derivatively on behalf of J&J. The pertinent legal standards and factors for such an analysis are set forth below.
Directors and officers are considered fiduciaries of a corporation. The two basic duties that each owes to a corporation are the common law duties of care and loyalty.	Directors and officers are considered fiduciaries of a corporation, and the two basic duties that each owes to a corporation are the common law duties of care and loyalty.
In New Jersey, the standard of care is defined in the following terms: "Directors and members of any committee designated by the board shall discharge their duties in good faith and with that degree of diligence, care and skill which ordinarily prudent people would exercise under similar circumstances in like positions." N.J.S.A. 14A:6-14(1). This requires a director or officer to make an informed business decision before taking action. More specifically, the duty of care requires officials to be attentive and to inform themselves of all material facts reasonably available to them regarding a decision before taking action. Liability for breach of the duty of care is measured by a standard of gross negligence. In re PSE&G, 173 N.J. at 296.	In New Jersey, the standard of care is defined in the following terms: "Directors and members of any committee designated by the board shall discharge their duties in good faith and with that degree of diligence, care, and skill which ordinarily prudent people would exercise under similar circumstances in like positions." N.J.S.A. 14A:6-14. This requires a director or officer to make an informed business decision before taking action. More specifically, the duty of care requires officials to be attentive and to inform themselves of all material facts reasonably available to them regarding a decision before taking action. Liability for breach of the duty of care is measured by a standard of "gross negligence." In re PSE&G, 173 N.J. at 291

2020 Report	2011 Report
The fiduciary duty of loyalty is not limited to cases involving financial or other cognizable conflicts of interest. It also encompasses cases where the fiduciary fails to act in good faith.	The fiduciary duty of loyalty is not limited to cases involving financial or other cognizable fiduciary conflict of interests. It also encompasses cases where the fiduciary fails to act in good faith.
In determining how to respond to the Shareholder Demand Letters and the Derivative Complaints, the Board should consider not only the likelihood of success on the merits in any litigation (i.e., whether J&J would ultimately prevail on claims for alleged breaches of the duty of care and/or the duty of loyalty by directors or officers), but also the impact on J&J of pursuing litigation as a whole – positive or negative. The judgment as to whether a particular lawsuit should be initiated or maintained can involve a balancing of many different factors including, among others, commercial, public relations, employee relations, and legal considerations.	In determining how to respond to derivative allegations, the Special Committee also considered not only the likelihood of success on the merits in any litigation (i.e., whether J&J would ultimately prevail on claims for alleged breaches of the duty of care and/or the duty of loyalty by directors or officers), but also the impact on J&J of pursing litigation as a whole -- positive or negative. The judgment as to whether a particular lawsuit should be initiated or maintained can involve a balancing of many different factors, including, among others, commercial, public relations, employee relations and legal considerations.

172. The striking similarities between the 2020 Report and 2011 Report corroborate that Lowenstein approached its investigation into Plaintiffs' Demand with a predetermined conclusion and steered the investigation toward that end. Moreover, the fact that several substantive sections of the 2020 Report were copied, nearly verbatim, from the 2011 Report demonstrates that Lowenstein did not objectively investigate the wrongdoing detailed in Plaintiffs' Demand or objectively

assess the strengths or weaknesses of potential derivative claims against J&J's current and former officers and directors for their role in the Company's unlawful opioid sales and marketing activities.

173. Lowenstein's failure to conduct a good faith investigation is of particular significance here because the Board merely adopted Lowenstein's findings and did not undertake any real Board-level effort to independently assess the issues raised in Plaintiffs' Demand. Further, nothing in the record suggests that any member of the Board even identified the fact that entire portions of the 2020 Report were recycled from Lowenstein's earlier report, much less raised concerns about the quality of Lowenstein's investigation and the 2020 Report, before agreeing to adopt the findings and recommendations therein.

3. Lowenstein's Prior Investigation Highlights the Deficiencies in the Investigation of Plaintiffs' Demand Here

174. Although the 2011 Report and investigation had many shortcomings, it is clear that Lowenstein and the Board did even *less* here to investigate, review, and/or remedy the wrongdoing alleged in Plaintiffs' Demand. Indeed, a comparison of the two investigations reveals striking deficiencies in the efforts of Lowenstein and the Board to investigate the wrongdoing set forth in Plaintiffs' Demand.

175. In connection with the 2011 investigation, the Board voted to appoint a special committee of independent directors to investigate the allegations raised in the prior demands and derivative complaints. According to the 2011 Report, the

four directors who served on the special committee "were chosen by the Board because they were the four outside directors who had most recently joined the Board at the time the Special Committee was formed." The members of the special committee also met at least eleven times to discuss the ongoing investigation and their evidentiary findings before making a recommendation to the Board. Here, the Board did not appoint a special committee to assist with the investigation of Plaintiffs' Demand. Instead, the Board delegated the entire investigation to Lowenstein and simply waited for Lowenstein to report back with its findings before rubber-stamping the predetermined recommendation that no action be taken.

176. In addition, as part of the 2011 investigation, Lowenstein and the special committee carefully evaluated whether any members of the Board or special committee lacked independence or disinterestedness such they should be excluded from participating in the decision to reject or pursue the prior demands and derivative complaints. As set forth in the 2011 Report, Lowenstein and the special committee "carefully considered whether they and the other outside directors of J&J's Board of Directors were independent and disinterested with respect to the subjects of the investigation" before deciding whether those members should participate in the investigation or have a say on whether the demands or derivative actions should proceed. In contrast, the 2020 Report does not indicate that Lowenstein undertook any analysis of the Demand Board's independence or disinterestedness. The failure

of Lowenstein to undertake such an analysis is particularly significant here because each member of the Demand Board faces a serious threat of personal liability for their actions (inaction) relating to the wrongdoing set forth in Plaintiffs' Demand.

177. There are also key differences in the scope of the two investigations. During the earlier investigation, Lowenstein obtained access to at least 23 million pages of documents, conducted thirty-nine interviews,[33] and met or communicated with seventeen lawyers from nine different law firms, as well as with five members of J&J's in-house counsel. In addition, Lowenstein was granted permission to meet with "various outside law firms that were either defending J&J and/or its subsidiaries in litigation or responding on behalf of J&J and/or its subsidiaries to requests/subpoenas by the SEC, DOJ, or Congress in the course of various investigations." In contrast, during the course of its investigation into Plaintiffs' Demand here, Lowenstein mostly relied on documents from other legal proceedings where the adequacy of J&J's internal controls was directly at issue, interviewed only twelve witnesses, and did not interview any of the various outside counsel retained to defend J&J, including the counsel retained in the MDL or Oklahoma actions.

[33] During the prior investigation, members of the special committee participated in a number of the interviews conducted by Lowenstein. In contrast, it appears that no member of the Board participated in any of the interviews conducted by Lowenstein during the course of its investigation into Plaintiffs' Demand.

178. Finally, although Lowenstein's prior investigation was deficient in many respects, it at least recognized that J&J could benefit from additional corporate governance reforms. As detailed in the 2011 Report, Lowenstein and the special committee recommended that the Board "create a new Regulatory and Compliance Committee," which "would permit the Audit Committee to focus on accounting, audit and financial issues while the new Committee focuses on Compliance systems and issues." Lowenstein and the special committee also "recommend[ed] that the Regulatory and Compliance Committee be authorized to retain outside expert consultants," and "in consultation with management and an expert consult ... develop metrics and a report card that would provide insight into and perspective on J&J's Compliance systems and organizations." In stark contrast here, Lowenstein's 2020 Report does not recommend that the Board take ***any*** steps to improve J&J's internal controls or reform its corporate governance. Rather, the 2020 Report concludes that J&J's current controls and governance structure are sufficient—despite the fact that J&J has already been found liable for its unlawful marketing and sale of opioids and remains on the hook for billions of dollars more in damages in thousands of lawsuits pending across the country.

179. The fact that Lowenstein's investigation yielded no recommendation that J&J strengthen its controls or governance structure, and that it failed to meet even the low-standard set by the firm's prior investigation, demonstrates

Lowenstein's lack of independence and underscores that its review of the matters set forth in Plaintiffs' Demand was not carried out in good faith.

C. The Board's Refusal Decision Was Not Based on a Reasonable, Good Faith Investigation Because It Failed to Consider Material Facts Demonstrating the Defendants' Liability

180. The Board's refusal of the Demand is not entitled to the business judgment presumption here because the investigation on which it is based was not reasonable under the circumstances and failed to gather and consider all reasonably available information. To conduct a reasonable and good faith investigation, a Board or special committee must investigate all theories of recovery asserted in plaintiffs' complaint and explore all relevant facts and sources of information that bear on the central allegations in the complaint. Ultimately, an investigation is unreasonable if it simply accepts defendants' version of disputed facts without consulting independent sources to verify defendants' assertions. In addition, if evidence suggests that the board members prejudged the merits of the suit based on prior exposure or familiarity with the derivative suit, and then conducted the investigation with the object of putting together a report that demonstrates the suit has no merit, demand refusal is wrongful.

181. Here, for the reasons discussed below, the Demand Board's refusal of Plaintiffs' Demand is not entitled to judicial deference.

1. The Demand Board Failed to Address Judicially Established Facts in the Oklahoma Trial Court Involving J&J Fiduciaries' Conduct, Including Oversight of Diversion Requirements

182. New Jersey corporate law establishes that a corporate insider may be held liable for personal acts or omissions that breach their duties of loyalty and cause damage to the corporation. N.J. Stat. §14A:6-14. This is the case despite the existence of any exculpatory clause in the Company's Certificate of Incorporation. N.J. Stat. §14A:2-7.

183. In an attempt to avoid statements made by the Company or its representatives in pleadings, depositions, or at trial that could be deemed admissions and used against the Company in collateral litigation, the Demand Board adopted a report focused entirely on the Attorney General of Oklahoma's litigation against J&J and Janssen in *State of Oklahoma, ex rel., Mike Hunter, Attorney General of Oklahoma v. Purdue Pharma L.P., et al.*, No. CJ-2017-816 (Okla. Dist. Ct.-Cleveland Cty.) ("Oklahoma Litigation"). Having adopted the 2020 Report's reasoning in its April 28, 2020 Refusal Letter, the Demand Board likewise assumed the 2020 Report's failure to consider facts and information that have already been judicially established by the Honorable Thad Balkman of the Oklahoma State District Court for Cleveland County (the "Oklahoma Trial Court").

184. In the Oklahoma Trial Court's Judgment After Non-Jury Trial, on August 26, 2019, the court determined that J&J was liable for public nuisance for its

dissemination of false and misleading promotion of its opioid products, through its subsidiaries.[34] Exhibit J at 25. According to the court's finding, the Company's "false, misleading, and dangerous marketing campaigns have caused exponentially increasing rates of addiction, overdose deaths, and Neonatal Abstinence Syndrome" which the court concluded were unlawful acts that "'annoys, injures, or endangers the comport, repose, health, or safety of others.'" *Id*. at 25-26 (citing 50 O.S. §1).

185. The 2020 Report complains that, in reaching this conclusion, the court relied "in significant part" on the 2004 FDA Warning Letter as a "red flag" that the messaging around the Company's opioid products was false and misleading. 2020 Report, Exhibit H at 94. While the Oklahoma Trial Court's decision does examine the implications of the 2004 Warning Letter, it is considered in conjunction with a number of other red flags indicating that the Company's internal controls were failing to halt the false and misleading campaign. Even a cursory reading of the Oklahoma Trial Court's decision reveals that the Demand Board, in adopting the 2020 Report, overlooked numerous other external and internal red flags that put J&J directors and officers on notice of the Company's illegal marketing practices.

186. The Board's failure to consider material, adjudicated facts from the Oklahoma Trial Court was unreasonable.

[34] The Judgment After Non-Jury Trial is attached hereto as Exhibit J.

a. The Demand Board Ignored *Internal* Red Flags Discussed By Oklahoma Trial Court

187. The Demand Board ignored numerous internal red flags deemed credible by the Oklahoma Trial Court.

188. First, the Oklahoma Trial Court found that J&J had hired a scientific advisory board that advised the Company that "many of the primary marketing messages Defendants used to promote opioids in general, and Duragesic specifically, were misleading and should not be disseminated." Exhibit J at 17. "Specifically, Defendants were advised not to market opioids, including fentanyl-based Duragesic, using messages related to abuse or with claims about supposedly low abuse potential." *Id*. "Defendants were advised that no data existed that could support these claims, that the data Defendants pointed to (DAWN data) was incapable of supporting these claims, that aggressively marketing OxyContin on this same basis was what had gotten Purdue 'in trouble,' that minimizing the risk of abuse of Duragesic was 'dangerous' due to its lethal nature, and that an increase of Duragesic sales would surely cause an increase in abuse of and addiction to the drug." *Id*. at 17-18.

189. Despite the conclusion of the internal scientific advisory board that the Company should "not include the abuse message" and "not sell opioids on the abuse issue," the Company, under the direction of its fiduciaries, did just that. The

Oklahoma Trial Court's finding illustrates a conscious disregard for the responsibility to prevent the dissemination of the misleading marketing messages.

190. The 2020 Report fails to address, and the Demand Board refused to investigate, the Oklahoma Trial Court's findings related to the defendants' conscious disregard that its marketing contained unsubstantiated claims that opioids could be safely used to treat chronic non-terminal pain, without a lack of evidence. Exhibit J at 19-21.

191. The 2020 Report also fails to address the Oklahoma Trial Court's finding regarding the spurning of internal scientific judgment that the Company's planned messaging on opioids would create abuse.

b. The Demand Board Ignored *External* Red Flags of False and Misleading Statements Discussed By Oklahoma Trial Court

192. The Demand Board also ignored ***external*** red flags deemed credible by the Oklahoma Trial Court.

193. The advice of the Company's internal scientific advisory board in 2001 came to fruition in 2004, when the FDA sent its Warning Letter. The 2020 Report's discussion of the Oklahoma Trial Court's examination of the 2004 Warning Letter is flawed. Instead of analyzing the Oklahoma Trial Court's finding, the 2020 Report seeks to attack the verdict.

194. In particular, the 2020 Report focuses solely on the Oklahoma Trial Court's finding that the FDA had concluded "Defendants' Duragesic file card made 'false and misleading safety claims and unsubstantiated effectiveness claims for Duragesic' and 'thus misbranded[ed] Duragesic in violation" of the Controlled Substances Act. 2020 Report, Exhibit H at 94 (citing Exhibit J at 18-19). But the Oklahoma Trial Court went much further in its assessment of the 2004 Warning Letter. The Oklahoma Trial Court noted that that the "FDA further mentioned that 'violations discussed' in the letter did not 'necessarily constitute an exhaustive list' and it was Defendants' responsibility to 'ensure that [its] promotional materials for Duragesic comply with each applicable requirement of the [Controlled Substances] Act and FDA implementing regulations.'" Exhibit J at 19. The Oklahoma Trial Court also noted that "[t]he file card was not the only piece of marketing that contained [false and misleading] materials," with "[e]vidence … presented of a variety of visual aids distributed in Oklahoma and utilized by sales representatives containing identical false and misleading messages." *Id*.

195. The 2020 Report does not discuss, and the Demand Board refused to further investigate, the wide-sweeping findings of the FDA in the 2004 Warning Letter and any changes to internal controls as a result. In fact, the Oklahoma Judgment discusses how the FDA requested the immediate cessation of the dissemination of J&J's opioid messaging, indicated violations were wide-reaching,

and did not provide an "exhaustive list" of examples as a result. Exhibit J at 19. The 2020 Report does not take into account the Oklahoma Trial Court's finding that the FDA determined the marketing to be a targeted strategy. *Id*. The fact that the 2020 Report analyzes the Oklahoma Trial Court's findings in such a narrow manner and ignores the Company's palliative measures in the face of the 2004 Warning Letter further reveals a Board working toward a predetermined result (i.e., no action taken against any of the Company's purported fiduciaries).

196. The 2020 Report also ignores the Oklahoma Trial Court's examination of Purdue's guilty plea in 2007 and ultimate finding that J&J's messaging related to addiction and abuse of opioids was "prone to mislead." Exhibit J at 28. In wholly conclusory fashion, the 2020 Report merely states that the "guilty pleas of Purdue and its officers in 2007 do not amount to 'red flags' giving rise to an obligation on the Company's part to investigate." 2020 Report, Exhibit H at 99. Without any analysis, the Demand Board adopted this conclusion.

197. The Demand Board side-steps the Oklahoma Trial Court's judicially established finding, demonstrating its eagerness to adopt an investigation that did not conflict with the predetermined conclusion it sought and further rendering the Board's refusal unreasonable.

c. The Demand Board Adopted a Biased Analysis of the Oklahoma Trial Court's Legal Conclusions

198. In addition to ignoring numerous red flags evident from the Oklahoma litigation and the findings of the Oklahoma Trial Court, the 2020 Report seeks to attack the Oklahoma Trial Court's legal conclusions.

199. First, the 2020 Report takes issue with the Oklahoma Trial Court's finding the Company's false and misleading campaign resulted in a public nuisance to Oklahoma residents. 2020 Report, Exhibit H at 93. In particular, the 2020 Report challenges the Oklahoma Attorney General's legal theories as "novel and expansive," and complains that they were applied "in an unprecedented fashion." *Id*. That is simply incorrect. The Oklahoma Trial Court thoroughly examined Oklahoma Supreme Court precedent, which supported the conclusion that "Oklahoma's nuisance law extends beyond the regulation of real property and encompasses the corporate activity complained of here." Exhibit J at 23 (citing *Epps v. Ellison*, 1921 OK 279, 82 Okla. 224, 200 P. 160, 161). As a court in equity, the Oklahoma Trial Court determined that "[t]he greater weight of the evidence shows that Defendants did, in fact, engage in such false and misleading marketing and the law is clear that such conduct qualifies as the kind of act or omission capable of sustaining liability under Oklahoma's nuisance law." *Id*. at 25.

200. Further, the use of a public nuisance theory to extend liability to defendants' conduct is not "unprecedented." As the Demand Board was no doubt

aware, the Ohio Attorney General posed a similar theory in the MDL before the U.S. District Court for the Northern District of Ohio. Judge Dan Aaron Polster of the Northern District of Ohio also recently denied defendants' motion for summary judgment challenging the public nuisance theory, finding that the Ohio Supreme Court had similarly recognized the "breadth of the absolute public nuisance cause of action."[35] Exhibit K at 2.

201. In addition, the Demand Board adopted the 2020 Report's reasoning that the Oklahoma Trial Court "did not take into consideration the holding of the West Virginia Supreme Court of Appeals" that FDA's 2004 Warning Letter stated the FDA's belief was not sufficient to establish that Janssen violated the Federal Food, Drug, and Cosmetic Act. 2020 Report, Exhibit H at 94. The Oklahoma Trial Court, however, did not rely solely on the FDA's 2004 Warning Letter in determining that defendants' actions caused harm to the health and safety of Oklahomans under Oklahoma public nuisance law, 50 O.S. §1, taking its own precedent into consideration.

202. The Demand Board likewise adopted a 2020 Report that seeks to challenge the Oklahoma Trial Court's reasoning in finding Duragesic harmful. The 2020 Report claims that the Oklahoma Trial Court failed to "evaluate the relative

[35] The Opinion and Order is attached hereto as Exhibit K.

potential for abuse represented by an opioid pill like OxyContin, which could be easily crushed, versus Duragesic's transdermal fentanyl patch." 2020 Report, Exhibit H at 94. The 2020 Report further contends that the Oklahoma Trial Court did not consider the Duragesic patch's "unique advantages" in ensuring "improved patient compliance due to less frequent administration and greater convenience for patients unable to swallow pills." *Id*. Contrary to this characterization of the court's decision, the Oklahoma Trial Court did, in fact, address similar arguments, finding that, internally, the defendants were advised that the minimization of risk of abuse of the Duragesic extended release patch was "dangerous," and that similar messaging about addiction "had gotten Purdue 'in trouble,"' for its marketing of OxyContin. Exhibit J at 18. The 2020 Report fails to address the Oklahoma Trial Court's finding, and the Demand Board failed to investigate any further.

203. In unreasonably challenging the Oklahoma Trial Court's decision, the 2020 Report also doubles down on the Board's position that "the medical community and government officials have recognized for several decades that the undertreatment of chronic pain is a public health concern." 2020 Report, Exhibit H at 95. The 2020 Report similarly states that "the concept of 'pseudoaddiction' received support in medical literature and in FDA-approved of labels for Duragesic, Nucynta ER, and Nucynta IR[.]" 2020 Report, Exhibit H at 95. But the Demand Board's investigation fails to directly address the Oklahoma Trial Court's decision

that it was the marketing campaigns promulgated by defendants that caused the overprescription and abuse of opioids sold by J&J and Janssen. Exhibit J at 17 ("Defendants' opioid marketing, in its multitude of forms, was false, deceptive and misleading"). The 2020 Report's logic, and the Demand Board's adoption thereof, is indicative of a Board with one objective: get to the predetermined result of no action being taken against any of the Company's purported fiduciaries.

204. With regard to the Oklahoma Trial Court's discussion of Noramco and Tasmanian Alkaloids' misconduct, the 2020 Report simply states that "Janssen's unbranded marketing campaigns did not start until 2008, thirty years after J&J acquired Noramco and twenty-seven years after it acquired Tasmanian Alkaloids." 2020 Report, Exhibit H at 96. The Demand Board failed to investigate J&J's failure to maintain internal controls over its subsidiaries' diversion of its Schedule II opioids. Under the 2020 Report's flawed logic, wrongdoing can only exist if it predated the marketing campaign. That is not the law. The Oklahoma Trial Court found that the Company and its subsidiaries were intertwined and were dependent on one another to increase sales of opioid products. Exhibit J at 6 (describing Noramco and Tasmanian Alkaloids as "members of Defendants' 'family of companies'" and "shared [J&J's] employees and resources that were 'required to operate the business.'"). The Oklahoma Trial Court further ound that "Noramco and Tasmanian Alkaloids were key parts of Defendants' 'pain management franchise' or

'pain franchise.'" *Id*. Noramco, in particular, "grew to become the No. 1 narcotic API supplier of oxycodone, hydrocodone, codeine and morphine in the United States," supplying a significant source of revenue for the Company until 2016. *Id*. at 9. The court, by virtue of its decision, found that Noramco and Tasmanian benefited from illegal marketing campaigns, which formed the basis of harm to the public.

205. The 2020 Report attacks the Oklahoma Trial Court's finding that the State Attorney General's expert witnesses were more credible in their testimony regarding causation. 2020 Report, Exhibit H at 96 ("the court relied heavily on statements by the State's expert witnesses."). In particular, the Oklahoma Trial Court found credible the expert testimony of the Chair of the Department of Psychiatry and Behavioral Sciences at Oklahoma State University Center for Health Sciences, Dr. Jason Beaman, and Commissioner of the Oklahoma Department of Mental Health and Substance Abuse Services, Terri White, among others, that the Company's contribution to oversupply and increases in sales of opioids increased opioid addiction and overdose deaths. Exhibit J at 20. The 2020 Report offers no "alternatives" as to what caused the dramatic increase in opioid abuse in Oklahoma. The 2020 Report's blatant disregard for the Oklahoma Trial Court's finding, and the Demand Board's adoption thereof, evidences the Board's desire to reach a predetermined result that minimized liability risk.

206. The Oklahoma Trial Court also found that "[t]here are no intervening causes that supervened or superseded Defendants' acts and omissions as a direct cause of the State's injuries, or otherwise defeat a finding of direct and proximate cause." Exhibit J at 29. The 2020 Report adopted by the Demand Board challenges this finding, pointing to Black Box warnings and labeling and REMS adopted by Janssen as adequate warnings that break the causation chain. 2020 Report, Exhibit H at 97. The Demand Board did not investigate whether the Company's risk management strategies had failed and the Black Box warnings did not mitigate dependency issues in the face of its false and misleading claims related to abuse and addiction of opioids. The 2020 Report attempts to mitigate the impact of the Oklahoma Trial Court's finding on supervening causes even with these warnings, which indicates a breakdown of internal controls. This breakdown is left unexamined by the Demand Board. In addition, even with Oklahoma law providing that a label provides adequate warnings to prescribing physicians, the Company still had a responsibility to prevent diversion and over-prescription. The Demand Board does not explore this duty whatsoever.

207. The Demand Board's lack of inquiry exemplifies its desire to reach a predetermined result that whitewashes the Oklahoma Trial Court's impactful findings and minimizes the $465 million in abatement damages awarded to the State.

This factual record does not support a finding that the Board's refusal of Plaintiffs' Demand was reasonable or made in good faith.

2. The Demand Board Ignored Other Litigation and Governmental Investigations

208. The 2020 Report's limited focus on the Oklahoma Litigation neglected any investigation concerning all other litigation and investigations involving J&J and/or Janssen and the roles the Board and J&J officers played in exposing the Company to liability in connection therewith.

209. In particular, the U.S. District Court for the Northern District of Ohio in the MDL made significant findings that mirror the judgment of the Oklahoma Trial Court. These findings went completely unexamined by Lowenstein and the Demand Board.

210. On September 4, 2019, the Honorable Dan Aaron Polster denied J&J's and Janssen's motion for summary judgment in the MDL, finding that plaintiffs had alleged facts sufficient to support a RICO claim against J&J and Janssen for participating in a criminal enterprise to pay kickbacks to doctors and disseminate false and misleading statements to promote opioid prescriptions and sales. In denying defendants' motion for summary judgment on causation, Judge Polster found: "Plaintiffs presented evidence sufficient to support a finding that each Manufacturer, including Janssen, engaged in misleading marketing activities that

resulted in a substantial increase in the supply of prescription opioids and proximately caused harm to Plaintiffs."[36] Exhibit L at 3-6 (citing Exhibit M).

211. In particular, similar to the Oklahoma Trial Court, Judge Polster discussed substantial evidence that J&J and Janssen "contributed substantial sums of money to third parties who published misleading statements about prescription opioid use." *Id.* at 3.

212. More damningly, the Northern District's decision provides further evidence that, contrary to the 2020 Report's finding, the Company's internal controls over diversion failed. Judge Polster found that "***each Manufacturer, including Janssen, failed to maintain effective controls against diversion [of opioids to the black market]***." Exhibit L at 6 (emphasis added). The 2020 Report fails to address this finding and the impact of the liability on the Company.

213. The 2020 Report also fails to consider Judge Declan P. Mansfield's April 2, 2019 denial of J&J's motion to dismiss in a Florida state action accusing J&J of misleading doctors into overprescribing opioids. The Florida Attorney General's complaint alleged that the companies knew or should have known there was no legitimate scientific basis for their claims to doctors and patients, but still continued deceptively marketing and selling the drugs. Any reasonable

[36] The Opinions and Orders are attached hereto as Exhibits L and M.

investigation of the Demand necessarily would have included an assessment of potential liability to the Company stemming from the Florida litigation.

214. As to government investigations into the Company's conduct related to opioid sales, the 2020 Report only states: "J&J continues to be subject to lawsuits and government investigations in connection with the matters raised in the Shareholder Demand Letters and Derivative Complaints." 2020 Report, Exhibit H at 15. Without explanation, the 2020 Report declares that any derivative litigation would jeopardize or create admissions to be used in collateral litigation. The Demand Board's adoption of this finding indicates the 2020 Report is being used to protect the Individual Defendants, as directors and officers of the Company, as opposed to investigating liability to the Company, and damages sustained by J&J due to the Board's wrongdoing.

215. The Demand Board accepts the 2020 Report's finding despite the fact that various government investigations, including a criminal probe by various federal prosecutors into J&J's violation of the Controlled Substances Act, have led the Company to offer $4 billion to join an agreement to resolve the matter. J&J's Chief Financial Officer, Joseph J. Wolk, acknowledged the inevitable liability during a June 23, 2020 conference call for the Bank of America Merrill Lynch Napa Healthcare Conference, stating the resolution would come "sometime this year." The 2020 Report completely ignores this looming settlement.

216. The 2020 Report does not address, nor does the Demand Board investigate, developments in either the U.S. Attorney's Office, the New York Attorney General, or the New York State Department of Financial Services' investigations, despite the Company admitting in the most recent Quarterly Report on Form10-Q filed with the SEC that it "is cooperating and producing documents in response to the various subpoenas and requests for information." Neither the 2020 Report nor the Refusal Letter indicate that the Demand Board or Lowenstein reviewed the documents subpoenaed by these investigators, or even a summary thereof. The utter disregard for the potential liability stemming from these investigation demonstrates a lack of good faith in the Demand Board's investigation of the Demand.

3. The 2020 Report Makes Clear that the Investigation Was Designed to Exonerate Defendants

217. The 2020 Report, adopted by the Demand Board, was based on an investigation designed to reach the predetermined conclusion that the allegations and claims in the Demand are without merit. Faced with damning factual allegations that defendants failed to heed red flags demonstrating the Company's illicit activity, the Demand Board caused Lowenstein to afford substantial deference to the Company's preexisting internal controls. The 2020 Report reads as a list of those supposedly adequate internal controls. The Demand Board's investigation, however,

is devoid of any meaningful analysis of whether those internal controls were failing and whether J&J's fiduciaries knew or should have known they were failing.

218. For example, in a section titled "Overview of J&J's Corporate Oversight of Health Care Compliance," the 2020 Report claims that "J&J strengthened its corporate oversight of compliance in the late 1990s to early 2000s" by established the Management Awareness and Review Systems translated into a management action plan ("MAP"). 2020 Report, Exhibit H at 29-30. The investigation made the conclusory observation that the MAP "promoted accountability at the operating company level by setting priorities and identifying resource plans with specific measurable actions and completion dates." *Id*. at 30. The 2020 Report does not specify how, or even if, this measure successfully resolved present issues with diversion and false and misleading marketing, which is at the heart of the misconduct discussed in the Demand. If anything, the 2020 Report reveals the opposite, readily admitting that the FDA's Warning Letter and the FDA's Division of Drug Marketing, Advertising, and Communications Warning Letter from 2004 about Duragesic's risks and the Company's problematic messaging did not get reported to the Audit Committee, or any committee of the Board. *Id*. at 61.

219. Similarly, the 2020 Report asserts that J&J "introduced a case management system to track and record on a Sensitive Issues Log all incoming calls on the Company's hotlines for reporting complaints of misconduct anonymously" in

2005. 2020 Report, Exhibit H at 32. But the 2020 Report does not state whether any issues were reported through the Log to management or the Board so as to prevent further issues with diversion and opioid abuse.

220. The 2020 Report also claims that J&J drafted "Standard Operating Procedures" in 2005 to "gather[] data on orders from the operational database system and then appl[y] an algorithm to those orders to flag potentially suspicious orders, which were then investigated and reviewed by either a manager responsible for DEA compliance or Quality Assurance." 2020 Report, Exhibit H at 84. Further, the 2020 Report claims that "monthly compliance meetings were held to enhance the suspicious order monitoring process." *Id*. However, the 2020 Report does not reveal whether reports or minutes about non-compliance issues with the Company's opioid products were reviewed by anyone at J&J or Janssen, or whether the SOPs were, in fact, revealing issues with DEA compliance.

221. The 2020 Report further avers that in 2007, the Company formed a "Triage Committee" chaired by the Chief Compliance Officer "to assure that serious legal, regulatory or compliance issues were reported to and addressed by senior management in a timely fashion." 2020 Report, Exhibit H at 33. But there is no indication that Lowenstein or the Demand Board interviewed anyone on the Triage Committee or reviewed documents pertinent to the Triage Committee's

investigations into serious legal, regulatory, or compliance issues related to the Company's sale of opioids since 2007.

222. There is also nothing in the 2020 Report addressing whether the Company's supposed "Escalation Procedure," supposedly adopted in 2008, revealed to the Vice President of Corporate Internal Audit any significant violations of J&J policy or law. 2020 Report, Exhibit H at 34. Nor does the 2020 Report reveal whether the Company's Health Care Compliance ("HCC") controls implemented in January 2010, in fact, "develop[ed] and implement[ed] efficient, effective, and sustainable programs to prevent and detect non-compliance with recognized legal and regulatory requirements, including, among other things, issues dealing with: FCPA, False Claims Act, off-label promotion, Anti-Kickback Statute, corporate integrity agreement/deferred prosecution agreement implementation, and interactions with health care providers and government officials." *Id.*

223. As to Janssen's supposed internal controls, the 2020 Report makes the conclusory determination that its "HCC group ensures that reviewed materials comply with company policies and procedures, industry standards, and applicable state and federal laws and regulations." 2020 Report, Exhibit H at 38. The 2020 Report also makes the perfunctory assertion that Janssen released in 2007 a "Policy on Product Promotion" to "provide essential product information to the physician regarding both the benefits and risks associated with company product usage." *Id.*

at 39-40. The investigation failed to test whether Janssen's HCC group or its internal product promotion policies revealed deficiencies that put Janssen in danger of non-compliance with FDA and DEA regulations.

224. With regard to statements made in Janssen's marketing, the 2020 Report contends that Janssen's Promotional Review Committee "vetted" the messages as "not misleading." 2020 Report, Exhibit H at 69-75. The messaging, drafted starting in 2008, includes language about addiction and abuse the FDA flagged as false and misleading in 2004. The Demand Board's investigation fails to analyze who constituted this committee and what was consulted in "vetting" the content of Janssen's marketing.

225. Through its litany of supposed internal controls, the Demand Board's investigation seeks to depict a corporation with adequate Board and management oversight. The investigation, however, is completely devoid of analysis into whether the Company's internal controls functioned properly. It was unreasonable for the Demand Board to simply accept the results of an investigation that failed to test whether these internal controls functioned properly in order to alert the Board and senior management of ongoing significant issues with the Company's diversion and illegal marketing of opioids.

4. The Demand Board's Refusal Letter Demonstrates that the Investigation Lacked a Good Faith or Reasonable Process

226. The April 28, 2020 Refusal Letter stated that "[t]he Board refused the demands investigated by Mr. Eakeley," adopting the 2020 Report's recommendations. The Refusal Letter does not indicate that the Demand Board reviewed anything beyond what Lowenstein outlined in its 2020 Report. The terse, one-page letter indicated that the Demand Board relied exclusively on the findings and conclusions of Lowenstein, without any independent verification of those findings. The Board's refusal of the Demand is not entitled to the business judgment presumption because the investigation on which it based its decision was not reasonable under the circumstances and failed to gather and consider all available information. The failures calling into doubt the reasonableness of the Demand Board's investigation found in the 2020 Report and Refusal Letter include:

(a) ***The Demand Board's Failure to Conduct an Independence Review***: Under N.J. Stat. §14A:3-6.5, only a majority vote of independent directors may terminate a derivative proceeding. It is crucial that a determination as to the independence of the voting directors is made. The Demand Board made no such determination. While the 2020 Report admits that a corporation "must establish that its decision to seek dismissal of the litigation was made by 'independent' directors," (2020 Report, Exhibit H at 11), the 2020 Report is completely devoid of any assessment of each individual voting Demand Board member. Instead, the 2020

Report merely states that "J&J's full Board is currently made up of fourteen members, thirteen of whom are 'independent' under the rules of the New York Stock Exchange." 2020 Report, Exhibit H at 28. Such an independence assessment falls well below the standards set by New Jersey law. The Refusal Letter follows suit, where it is apparent the Demand Board conducted no such assessment at the time of its determination to decline Plaintiffs' Demand. *See* Exhibit I. The Demand Board's decision to decline to pursue the derivative claims is, therefore, not entitled to deference.

(b) ***Lack of In-Person Interviews of Adverse Witnesses***: Lowenstein only interviewed in person internal J&J witnesses, including three defendants—Gorsky, Mulcahy, and Prince. While these were necessary interviews, each of these witnesses had a strong incentive to belittle the claims and justify the Board's decision-making, and to shirk blame for the abuse and addiction associated with the Company's false and misleading opioid marketing. The Demand Board failed to interview any of the other alleged wrongdoers or key investigators looking into the defendants' misconduct, relying instead on testimony transcripts taken in the Oklahoma Litigation and depositions taken from the Oklahoma Litigation and Ohio MDL. The 2020 Report itself did not provide a comprehensive review of what was asked and learned in the course of these investigations. There is no basis in the record to discern anything meaningful about the scope, depth or quality of the

interviews, or to conclude that the "interviews" actually conducted consisted of more than "soft-ball" questions with no follow-up, effort to refresh recollection or to impeach with conflicting facts, documents or testimony. There is no indication in the 2020 Report that the Board attended or supervised the witness interviews that Lowenstein did conduct. The utter lack of explanation and examination raises significant doubt as to the diligence with which the Demand Board investigated and responded to the Demand.

(c) ***The Refusal Letter Fails to Specify the Demand Board's Meetings Regarding the Investigative Process***: As the Refusal Letter readily admits, the Demand Board met only once on April 23, 2020, to discuss the 2020 Report's findings. Without any analysis, the Refusal Letter states that the demands investigated were "contrary to the best interests of the Company." *See* Exhibit I. As the Refusal Letter indicates that the Demand Board met on only single occasion with the sole intent to reject the Demand, the Demand Board's reasoning is not entitled to a finding of reasonableness.

(d) ***Lack of Demand Board's Review of Documents Relied on By Lowenstein***: Neither the 2020 Report nor the Refusal Letter state which documents, if any, were considered by the Demand Board from Lowenstein's investigation. There is no evidence that the Demand Board even reviewed a summary of those

documents. The Demand Board's investigation was perfunctory at best and not entitled to a finding of reasonableness.

(e) ***The Demand Board's Failure to Obtain Tolling Agreements During the Pendency of Its Investigation***: The Refusal Letter does not state, and the Demand Board makes no mention of, any attempt to secure agreements to toll the running of the statute of limitations during the pendency of the Demand Board's investigation. The Demand Board was required, but failed, to consider the running of the statute of limitations in exercising its business judgment and, therefore, unnecessarily jeopardized the Company's ability to pursue potentially valuable claims.

COUNT I

Against the Individual Defendants for Breach of Fiduciary Duty

227. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

228. The Individual Defendants owed and owe J&J fiduciary obligations. By reason of their fiduciary relationships, the Individual Defendants owed and owe J&J the highest obligation of good faith, fair dealing, loyalty, and due care.

229. The Individual Defendants and each of them, violated and breached their fiduciary duties of candor, good faith, and loyalty. More specifically, the Individual Defendants violated their duty of good faith by creating a culture of

lawlessness within J&J, and/or consciously failing to prevent the Company from engaging in the unlawful acts complained of herein.

230. The Officer Defendants either knew, were reckless, or were grossly negligent in disregarding the illegal activity of such substantial magnitude and duration. The Officer Defendants knowingly, recklessly, or with gross negligence caused or allowed the Company to engage in an illicit marketing scheme to expand the market and increase demand for opioids. The deceptive marketing scheme worked—opening the floodgates of opioid use and abuse. By failing to prevent the Company from engaging in this deceptive conduct despite repeated warnings, the Officer Defendants effectively condoned this unlawful activity. Accordingly, the Officer Defendants breached their duty of care and loyalty to the Company.

231. The Director Defendants, as directors of the Company, owed J&J the highest duty of loyalty. These defendants breached their duty of loyalty by knowingly or recklessly causing or allowing the Company to engage in an illicit marketing scheme to expand the market for opioids and unlawfully increase its revenues from opioids. By failing to prevent the Company from engaging in this deceptive conduct despite repeated warnings, the Director Defendants effectively condoned this unlawful activity. Accordingly, these defendants breached their duty of loyalty to the Company.

232. As a direct and proximate result of the Individual Defendants' breaches of their fiduciary obligations, J&J has sustained significant damages, as alleged herein. As a result of the misconduct alleged herein, these defendants are liable to the Company.

233. Plaintiffs, on behalf of J&J, have no adequate remedy at law.

COUNT II

Against the Individual Defendants for Unjust Enrichment

234. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

235. By their wrongful acts and omissions, the Individual Defendants were unjustly enriched at the expense of and to the detriment of J&J. The Individual Defendants were unjustly enriched as a result of the compensation and director remuneration they received while breaching fiduciary duties owed to J&J.

236. Plaintiffs, as stockholders and representatives of J&J, seek restitution from these defendants, and each of them, and seek an order of this Court disgorging all profits, benefits, and other compensation obtained by these defendants, and each of them, from their wrongful conduct and fiduciary breaches.

237. Plaintiffs, on behalf of J&J, have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of J&J, demand judgment as follows:

A. Against all of the defendants and in favor of the Company for the amount of damages sustained by the Company as a result of the defendants' breaches of fiduciary duties and unjust enrichment;

B. Directing J&J to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect J&J and its stockholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for stockholder vote, resolutions for amendments to the Company's Bylaws or Articles of Incorporation and taking such other action as may be necessary to place before stockholders for a vote of the following corporate governance policies:

1. a proposal to strengthen the Company's controls over marketing and sales of opioids;

2. a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater stockholder input into the policies and guidelines of the Board;

3. a provision to permit the stockholders of J&J to nominate at least three candidates for election to the Board;

4. a proposal to appoint additional independent board members with established reputations in the pharmaceutical industry and with substantial experience in governance, risk and compliance issues;

5. a proposal to enhance and/or augment the audit, risk and compliance committees of the Board to oversee internal controls and compliance processes and procedures;

6. a proposal to ensure that the Chief Compliance, Risk and Legal Officer(s) and other company leadership have (a) necessary subject matter and regulatory expertise; (b) direct reporting authority to the Board; and (c) adequate autonomy and resources to carry out their responsibilities;

7. a proposal to review and implement revised codes of conduct, policies and procedures, training, integrity hotlines, auditing and monitoring processes and procedures;

8. a proposal to review and implement policies and procedures for escalating internal and regulatory issues internally and to the Board;

9. a proposal to review and implement the confidential reporting structure and investigative process of complaints within the company;

10. a provision to control insider selling and conflicts of interest, including potential investigative conflicts of interest; and

11. a proposal to enhance security and cybersecurity around data privacy, patient information, and system security.

C. Production of documents and other discovery permitted by New Jersey law relevant to determining what steps the Board took to inform themselves of the

Plaintiffs' Demand and the reasonableness of its decision, including (without limitation) the following categories of documents:

1. Board meeting minutes and communications reflecting the Board's evaluation of its members;

2. Board meeting minutes and communications reflecting the Board's evaluation of Lowenstein and the firm's independence, including the selection, retention, and compensation of Lowenstein;

3. all drafts of the 2020 Report;

4. transcripts, summaries, and notes of witness interviews reviewed by the Board;

5. communications between members of the Board concerning the underlying wrongdoing alleged in Plaintiffs' Demand;

6. documents, or any summaries thereof, relied on by Lowenstein and reviewed by the Board;

7. documents from experts or other consultants retained by Lowenstein or the Board in connection with the investigation of Plaintiffs' Demand; and

8. any memoranda, notes, or summaries of the witness interviews conducted by Lowenstein.

D. Extraordinary equitable and/or injunctive relief as permitted by law, equity, and state statutory provisions sued hereunder, including attaching, impounding, imposing a constructive trust on, or otherwise restricting the proceeds of defendants' trading activities or their other assets so as to assure that Plaintiffs on behalf of J&J has an effective remedy;

E. Awarding to J&J restitution from defendants, and each of them, and ordering disgorgement of all profits, benefits, and other compensation obtained by the defendants;

F. Awarding to Plaintiffs the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

G. Granting such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury.

Dated: July 29, 2020

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**pro hac vice motions to be filed*

1458289

CERTIFICATE OF SERVICE

I, Serina M. Vash, hereby certify that on July 29, 2020, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered counsel.

HERMAN JONES LLP

/s/ *Serina M. Vash*
SERINA M. VASH (NJ Bar. No. 041142009)